MEDICARE ANNUAL REPORT TO THE CONGRESS

Fiscal Year 1984

PUBS
RA
412
.3
A323
1984

The following reports contained in this volume:

- Medicare Annual Report
- End Stage Renal Disease Program Report
- Medicare/Medicaid Validation Survey of Hospitals Accredited by the Joint Commission on Accreditation of Hospitals Report
- Medigap Voluntary Certification Program Report

MEDICARE ANNUAL REPORT TO THE CONGRESS

Fiscal Year 1984

RA
412.3
.A323
1984
c.3

The following reports contained in this volume:

- Medicare Annual Report
- End Stage Renal Disease Program Report
- Medicare/Medicaid Validation Survey of Hospitals Accredited by the Joint Commission on Accreditation of Hospitals Report
- Medigap Voluntary Certification Program Report

TABLE OF CONTENTS

PAGE

INTRODUCTION..... vii
EXECUTIVE SUMMARY.....viii

CHAPTER I. PROGRAM OPERATIONS..... 1

BENEFICIARIES..... 1
HEALTH CARE RESOURCES..... 1
BENEFIT PAYMENTS..... 2
CLAIMS PROCESSING PERFORMANCE..... 3
DISTRIBUTION OF CLAIMS..... 3
CLAIMS PROCESSING TIMELINESS..... 5
CLAIMS PENDING..... 6
CONTRACTOR ADMINISTRATIVE COST EXPERIENCE..... 7
CONTRACTOR PERFORMANCE..... 7

CHAPTER II. PROGRAM ADMINISTRATION..... 11

PREPAYMENT PLANS..... 11
QUALITY AND APPROPRIATENESS OF CARE..... 11
MEDICAL REVIEW IN HOSPITALS..... 11
MEDICAL REVIEW OF PART B SERVICES..... 13
MEDICAL REVIEW OF OTHER THAN INPATIENT HOSPITAL SERVICES... 14
STANDARDS AND CERTIFICATION..... 14
SECOND SURGICAL OPINION PROGRAM..... 15
IMPROVING UTILIZATION SAFEGUARDS..... 15
BENEFICIARY SERVICES..... 16
QUALITY CONTROL PROGRAMS..... 16
HOSPITAL/REIMBURSEMENT REVIEW PROGRAM (HOSP-RRP) AND HOME HEALTH AGENCY REIMBURSEMENT REVIEW PROGRAM (HHA-RRP)..... 17
INTERIM PAYMENT REVIEW PROGRAM (IPRP)..... 17
MEDICARE PART B QUALITY ASSURANCE PROGRAM..... 18
TARGET RATE IMPLEMENTATION MONITORING (TRIM) PROGRAM AND HOME OFFICE (HO-TRIM) PROGRAM..... 18
OPERATIONAL REVIEWS..... 19
HOME HEALTH SERVICES..... 19
PARENTERAL/ENTERAL SERVICES..... 20
PACEMAKER REPLACEMENTS..... 21
MEDICARE SECONDARY PAYER..... 21
SURVEY AND CERTIFICATION..... 22
MEDICAL REVIEW/UTILIZATION REVIEW..... 22

CHAPTER III. POLICY DEVELOPMENT..... 23

IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM..... 23
REFINEMENTS TO PPS..... 23
RURAL REFERRAL CENTERS..... 24
HOSPITALS IN AREAS REDESIGNATED AS RURAL..... 25
CENSUS DIVISION BOUNDARIES..... 25

TABLE OF CONTENTS (CONTINUED)

PAGE

DEVELOPMENT OF NEW WAGE INDEX..... 25
PPS ADJUSTMENTS, EXCEPTIONS, AND EXCLUSIONS..... 26
SPECIAL PAYMENT ARRANGEMENTS FOR SOLE COMMUNITY HOSPITALS.. 27
SPECIAL PAYMENT ARRANGEMENTS FOR CANCER HOSPITALS..... 27
PROVIDER PAYMENT APPEALS..... 28
PROSPECTIVE PAYMENT BENEFICIARY CHARGES..... 28
PROVIDER APPEALS OF DRG ASSIGNMENTS..... 29
OTHER RULE CHANGES..... 29
OTHER INITIATIVES..... 29
COST LIMITS FOR SKILLED NURSING FACILITIES..... 29
COST LIMITS FOR HOME HEALTH AGENCIES..... 29
COSTS INCURRED FOR UNION ACTIVITIES..... 30
COST REPORT QUESTIONNAIRE..... 30
SWING-BED HOSPITAL INSTRUCTIONS..... 31
PARTICIPATING PHYSICIANS AND THE FEE FREEZE..... 31
PAYMENT FOR CLINICAL DIAGNOSTIC LAB TESTS..... 31
COVERAGE OF HEMOPHILIA CLOTTING FACTORS..... 32
SPECIAL ENROLLMENT PERIOD FOR THE WORKING AGED..... 32
READABILITY STANDARDS FOR PART B REVIEW DETERMINATION LETTERS..... 32
REPRESENTATION OF BENEFICIARIES IN PART A APPEALS..... 32
COVERAGE OF HEART TRANSPLANTATION..... 32
CONFIDENTIALITY AND DISCLOSURE..... 33
PROVIDER REIMBURSEMENT APPEALS..... 33

CHAPTER IV. LEGISLATIVE HIGHLIGHTS: THE DEFICIT REDUCTION ACT OF 1984..... 35

INTRODUCTION..... 35
MEDICARE REIMBURSEMENT AND BENEFIT CHANGES..... 35
OTHER CHANGES..... 37

CHAPTER V. REPORT ON RESEARCH, DEMONSTRATIONS, AND EVALUATIONS..... 39

INTRODUCTION..... 39
HOSPITAL PAYMENT..... 40
PHYSICIAN PAYMENT..... 41
LONG-TERM CARE..... 42
RESEARCH..... 42
DEMONSTRATIONS..... 45
ALTERNATIVE PAYMENT SYSTEMS..... 46
PROGRAM ANALYSIS AND EVALUATION..... 47
PROGRAM ANALYSIS..... 47
EVALUATION..... 48
COVERAGE..... 49
DATA BASE AND STATISTICAL ACTIVITIES..... 50
PREVENTION..... 51
HCFA'S R&D PUBLICATIONS PROGRAM..... 52

TABLE OF CONTENTS (CONTINUED)

PAGE

CHAPTER VI. YEAR-END TABLES..... 55

CHAPTER VII. END-STAGE RENAL DISEASE PROGRAM (CALENDAR YEAR 1984)... 61

INTRODUCTION..... 61
DATA COLLECTION..... 63
ESRD FACILITY PROFILE..... 65
MINIMUM UTILIZATION RATES..... 68
RENAL DIALYSIS CENTERS..... 68
TRANSPLANT CENTERS..... 69
MINIMUM UTILIZATION RATE STUDY..... 70
DIALYSIS..... 70
PATIENT PROFILE..... 70
CAPD NATIONAL PATIENT REGISTRY..... 76
TRANSPLANTS..... 77
TRANSPLANT TYPES..... 79
TRANSPLANT FAILURES..... 82
COST OF HOSPITALIZATION FOR ANCILLARY PROBLEMS..... 83
DATA..... 83
RESULTS..... 83
KIDNEY ACQUISITION COSTS..... 85
DONOR TYPE..... 85
INDEPENDENT ORGAN PROCUREMENT..... 88
MEDICARE PAYMENT RATES..... 90
REIMBURSEMENT FOR DIALYSIS AND RELATED SERVICES..... 90
EXCEPTION SYSTEM..... 91
TRANSPLANT PROCEDURES..... 92
PROJECTED ENROLLMENT AND BENEFIT PAYMENTS..... 92
PATIENT SURVIVAL..... 93
DATA..... 94
RESULTS..... 94
MEDICARE INPATIENT HOSPITAL USE, BY AGE INTERVAL..... 100
PERSONS ON DIALYSIS FOR THE ENTIRE ELIGIBLE YEAR..... 102
PERSONS RECEIVING TRANSPLANTS IN 1984..... 102
PERSONS RECEIVING A TRANSPLANT IN A YEAR PRIOR TO 1984, WITH A FUNCTIONING GRAFT THROUGHOUT 1984..... 103
PERSONS RECEIVING A TRANSPLANT IN A YEAR PRIOR TO 1984, WITH A KIDNEY GRAFT FAILURE IN 1984..... 105
COSTS SAVINGS AND OTHER ESRD EXPERIMENTS..... 105
NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANT STUDY..... 106
ASSESSMENT OF COMPETITIVE HEALTH INSURANCE PROPOSALS IN THE END-STAGE RENAL DISEASE PROGRAM..... 107
DEVELOPING INCENTIVE SYSTEMS TO INCREASE THE SUPPLY OF CADAVERIC KIDNEYS FOR TRANSPLANTS..... 108
RELATIVE EFFECTIVENESS AND COST OF TRANSPLANTATION AND DIALYSIS IN END-STAGE RENAL DISEASE..... 108
ORGAN DONOR EDUCATION PROJECT..... 109

PAGE

COSTS, OUTCOMES, AND COMPETITION IN THE END-STAGE RENAL DISEASE PROGRAM..... 109
END-STAGE RENAL DISEASE NUTRITIONAL THERAPY STUDY..... 110
SEVERITY OF ILLNESS IN THE END-STAGE RENAL DISEASE POPULATION IN NORTHERN FLORIDA..... 111
COMPARISON OF QUALITY OF LIFE OF END-STAGE RENAL DISEASE PATIENTS..... 111
WAIVER FOR THE NORTHWEST KIDNEY CENTER, SEATTLE, TO BE REIMBURSED DIRECTLY FOR PROVIDING HOME DIALYSIS TRAINING SERVICES..... 112
COMPARATIVE ANALYSIS OF THE COST AND OUTCOMES OF KIDNEY TRANSPLANTS..... 113
ESRD NETWORK ORGANIZATIONS..... 113

CHAPTER VIII. REPORT OF MEDICARE VALIDATION SURVEYS OF HOSPITALS ACCREDITED BY THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS (JCAH)..... 117

INTRODUCTION..... 117
STATUTORY BACKGROUND..... 117
ACCREDITATION PROCESS..... 117
VALIDATION AND ALLEGATION PROCESS..... 118
VALIDATION FINDINGS..... 118
LIFE SAFETY CODE..... 119
GENERAL HEALTH AND SAFETY..... 120
SUBSTANTIAL ALLEGATION FINDINGS..... 121
CONCLUSION..... 122

CHAPTER IX. MEDIGAP VOLUNTARY CERTIFICATION PROGRAM REPORT (Section 1882(f)(2) of Title XVIII)..... 123

BACKGROUND..... 123
PROVISIONS OF MEDIGAP LAW..... 123
THE VOLUNTARY CERTIFICATION PROGRAM..... 124
PARTICIPATION..... 124
IMPACT..... 125
PENALTY PROVISIONS..... 125
IMPLEMENTATION..... 126
ACTIVITY IN FY 84..... 126
DIFFICULTIES IN PROSECUTION..... 127

INTRODUCTION

The Health Care Financing Administration (HCFA) of the Department of Health and Human Services (HHS) is responsible for administering the Medicare program, which provides hospital and medical insurance to the Nation's elderly and disabled.

In 1984, national spending for health care reached $387 billion, amounting to 10.6 percent of the gross national product. Of this amount, Medicare paid 16.7 percent of health care expenditures.

Nationally, hospital costs were the single most expensive item of personal health care spending, reaching $158 billion, or 41 percent of health care expenditures. In Medicare, hospital costs accounted for 72.8 percent of all costs both in 1983 and 1984, even though admissions and length of stay were down from previous years.

Medicare serves 97.5 percent of those over age 65. This figure has been growing slightly over several years. In addition, the program covers 2.9 million disabled individuals.

When Medicare began in 1966, 9.4 percent of the population was 65 years of age or over. By 1984, by actuarial estimates, 11.6 percent of the population was elderly. The increase in the proportion of the population eligible for Medicare, coupled with significant rises in medical care prices and intensity of services delivered, has put the solvency of the Medicare hospital insurance trust fund in jeopardy.

The recent institution of the prospective payment system (PPS) is intended to help the situation, although PPS is not the complete answer. As the elderly population grows and fiscal pressures mount, careful administration of the program becomes more important.

This report summarizes Medicare activity and HCFA's initiatives during fiscal year (FY) 1984.

PROGRAM OPERATIONS

BENEFICIARIES

As of July 1, 1984, 27.6 million aged persons and 2.9 million disabled persons under 65, a total of 30.5 million, were entitled to hospital insurance (Part A) and/or supplementary medical insurance (Part B). Of the 30.5 million enrollees, 30.0 million had Part A coverage and 29.4 million were enrolled in Part B. Of beneficiaries aged 65 and over, 95 percent were covered by both Parts A and B; 92 percent of disabled beneficiaries were covered by both parts.

HEALTH CARE RESOURCES

As of July 1, 1984, 6,675 hospitals with 1,144,142 beds were participating in Medicare, as were 5,952 skilled nursing facilities (SNFs), 4,684 home health agencies (HHAs), and 3,801 independent laboratories. Other participating facilities included 420 rural health clinics, 155 ambulatory surgical centers, 132 hospices, and 1,368 facilities or units providing services to program beneficiaries requiring maintenance dialysis or kidney transplant.

BENEFIT PAYMENTS

During FY 84, Medicare paid $41.5 billion in benefits under hospital insurance (Part A) and $19.5 billion under medical insurance (Part B), a total of $61.0 billion. This represents an increase of 9.6 percent over FY 83 total benefit payments of $55.6 billion ($38.1 billion under Part A and $17.5 billion under Part B). Inpatient hospital care accounted for 94 percent of all Part A payments. Payments for physician and suppliers' services accounted for 74 percent of Part B payments.

CLAIMS PROCESSING PERFORMANCE

Overall, the volume of Medicare claims rose 7.9 percent in FY 84, to 279.4 million. Of this total, intermediaries received 50.4 million claims, a decrease of 0.4 percent below FY 83. Claims received by carriers rose at a rate of 9.9 percent, to a total of 229.0 million.

The majority (58.9 percent) of claims received by intermediaries during FY 84 were requests for payment for outpatient services provided to Medicare beneficiaries. Inpatient hospital claims accounted for 24.1 percent of claims received, while HHA and SNF claims accounted for

10.4 percent and 1.8 percent, respectively. The remaining 4.8 percent were claims submitted for ancillary and other miscellaneous services payable under Part B.

Of claims received by carriers, 55.9 percent were submitted by physicians and suppliers on assignment. Unassigned claims accounted for 43.3 percent of claims, while 0.9 percent were submitted by provider-based physicians and group practice prepayment plans.

The percent of claims submitted by physicians and suppliers on assignment increased from 51.0 to 55.9 percent. In contrast, the percent of claims submitted unassigned by beneficiaries dropped slightly, from 44.3 to 43.3 percent, while those submitted by provider-based physicians and group practice prepayment plans fell sharply, from 4.8 to 0.9 percent.

The average claims processing time for intermediaries increased from 7.0 days to 8.4 days. Carriers showed an increase in yearly average claims processing time from 9.9 days to 11.5 days. The average monthly percentage of claims pending over 30 days for intermediaries increased from 11.6 to 15.0 percent. Carriers' average percentage of claims pending over 30 days increased from 9.0 to 12.1 percent. During FY 84, the volume of pending claims rose 27.9 percent for intermediaries and 59.7 percent for carriers.

CONTRACTOR ADMINISTRATIVE COST EXPERIENCE

The FY 84 intermediary processed workload increased 3.1 percent over the previous fiscal year, whereas total cost (excluding audit) increased 13.1 percent. This increase in cost was due to increased payment safeguards and productivity investment efforts. The unit cost for all operations (including audit) increased 51 cents, and the unit cost for operations excluding audit increased 34 cents. For carriers, the processed workload increased 10.1 percent. Total cost increased 6.2 percent, while the unit cost decreased by 8 cents.

CONTRACTOR PERFORMANCE

HCFA evaluates the performance of Medicare contractors by using the Contractor Performance Evaluation Program (CPEP). The CPEP is comprised of pre-established performance criteria and standards with specific acceptance quality levels designated for each discrete area of performance measured.

In FY 84, the Part A CPEP measured intermediaries' performance in the following major areas: bill processing, provider reimbursement, contract management, prospective payment-medical review, and prospective payment base-year

audit. The Part B CPEP measured performance in the following major areas: claims processing, program payment, and contract management.

The CPEP also reflected HCFA's renewed emphasis on controlling benefit payments, reducing administrative costs, and assuring that contractors do not compromise the quality of their work to achieve savings. Review areas were augmented and acceptable quality levels were increased.

PROGRAM ADMINISTRATION

PREPAYMENT PLANS

Health maintenance organizations (HMOs) are a growing alternative to traditional forms of health care delivery. An HMO is an organization that provides its members comprehensive health services, without regard to frequency or extent of services, in return for predetermined, fixed premiums paid by members. During FY 84, the number of contracting HMOs increased from 75 to 103, and Medicare membership in HMOs increased 92 percent, from 184,093 to 354,198. Total payments to contracting HMOs more than doubled, from $245 million in FY 83 to $492 million in FY 84.

QUALITY AND APPROPRIATENESS OF CARE

A major goal of the Medicare program is to assure that its beneficiaries receive appropriate health care services. In addition to making sure that the actual care delivered to beneficiaries meets accepted professional standards, HCFA must ensure that services are necessary and are performed at the most economical level consistent with accepted standards of care.

To help meet these goals, in the last quarter of FY 84, HCFA instituted the Utilization and Quality Control Peer Review Organization (PRO) Program. The PRO program, which will be fully implemented in FY 85, was initially limited to medical review of inpatient hospital care under the prospective payment system.

Medical review of Part B services was conducted by carriers through a two-tiered approach using prepayment utilization screens and postpayment review. Fiscal intermediaries carried out a review of admissions for other than inpatient hospital services (e.g., SNFs, HHAs, hospices).

Medicare also requires that participating facilities be structurally safe, clean, properly staffed, and provide needed services and that the care provided meet accepted professional standards. To participate in the Medicare program, health care facilities must meet conditions of participation that specifically define those health and safety standards. To ensure that those standards are met,

States conduct surveys under contract with HHS, including validation and allegation surveys of hospitals accredited by the Joint Commission on Accreditation of Hospitals (JCAH) or the American Osteopathic Association (AOA).

In FY 84, HCFA continued its program to encourage beneficiaries to seek a second opinion before having nonemergency surgery. Since its inception in 1978, this program has helped reduce the incidence of unnecessary surgery.

BENEFICIARY SERVICES

An integral part of the Agency's success in administering the Medicare program is its efforts to inform and educate beneficiaries about HCFA programs and services available to them. This is accomplished through pamphlets, handbooks, brochures, telephone hot lines, and through open communication with beneficiary representation groups.

QUALITY CONTROL PROGRAMS

HCFA monitors the quality of Medicare program administration through an array of payment review and other programs. Areas monitored include the quality of provider cost report settlement by intermediaries; carrier claims processing performance; intermediary performance in calculating and adjusting PPS interim rates and bill payment computations; the quality of base-year audit; and computations of target amount per discharge under the prospective payment system.

In FY 84, a total of 503 hospitals and 38 home office base-period audits were reviewed. The total estimated dollar adjustments identified were $28.1 million. The adjustments consisted of $26.0 million of provider overpayments and $2.1 million of provider underpayments.

OPERATIONAL REVIEWS

Operational reviews assess the need for policy and operational reforms in vulnerable program areas. To inform HCFA senior management of the financial and operational implications of policy and management decisions, HCFA staff perform studies of selected program and policy issues through extensive research of inhouse information supplemented by additional documentation and onsite review.

Reviews conducted in 1984 included the accuracy of home health coverage determinations made by HCFA's fiscal intermediaries; the effectiveness of coverage guidelines and carrier reimbursement practices related to parenteral/enteral services; pacemaker replacements; Medicare as secondary payer; long-term care survey and certification; and utilization of payment screens by carriers.

POLICY DEVELOPMENT

IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM

The Social Security Amendments of 1983 (Public Law 98-21) introduced one of the most sweeping changes in the Medicare program that had occurred since it began 19 years ago. It changed the method of payment for inpatient hospital services from the retrospective reasonable-cost basis to a prospective payment system (PPS) based on 468 diagnosis-related groups (DRGs) applied at the time of a patient's discharge from the hospital.

Implementation of PPS began in 1984 and is to be phased in over 3 years. Interim regulations were published on September 1, 1983, and final regulations followed on January 3, 1984. Implementation has proceeded smoothly, with no significant problems or disruptions during the initial phase of the transition. As of September 30, 1984, 5,405 hospitals--81 percent of all Medicare hospitals--were participating under PPS.

REFINEMENTS TO PPS

After developing and implementing the major elements of the system, HCFA began to refine it and correct inequities that had become apparent. Additional modifications were mandated by the Deficit Reduction Act of 1984 (DEFRA).

Regulations provide criteria that permit certain rural hospitals to qualify as rural referral centers. New regulations also provide a special adjustment for hospitals in areas redesignated as rural and clarify the census division to which a hospital belongs if it is located in an urban area that crosses census division boundaries. Also, in accordance with the requirements of DEFRA, HHS is undertaking a study to develop an improved wage index that explicitly addresses the part-time employment issue.
The law instituting the prospective payment system excludes several kinds of hospitals and hospital units from PPS. Regulations issued in FY 84 authorized an additional temporary exclusion for alcohol and drug treatment hospitals and distinct-part units. As mandated by law, a study is under way to determine a method to include in PPS hospitals located outside the 50 States and the District of Columbia.

Regulations were also issued to implement special payment arrangements for sole community hospitals and cancer hospitals. Other regulations related to PPS dealt with provider payment appeals, beneficiary charges for medically unnecessary care, day-outlier payments for transfer cases, and additional payments to hospitals for inpatient renal dialysis. HCFA also developed an appeals mechanism to allow a hospital to challenge a DRG assigned by an intermediary or medical review entity.

OTHER INITIATIVES

Other policy development initiatives in 1984 addressed cost limits for skilled nursing facilities and home health agencies. Regulations were published to implement the DEFRA requirement that routine service cost limits for hospital-based and freestanding SNFs be similar to those in effect before enactment of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). A notice was published incorporating into the cost limits for HHAs changes in inflation estimates and metropolitan statistical area (MSA) designations, expanding the adjustment for prevailing wage levels to all labor-related costs, and excluding extremely high and low costs in establishing the limits.

The Provider Cost Report Questionnaire, Form HCFA-339, was issued in February 1984. The questionnaire was designed to assist providers in providing acceptable cost reports.

Instructions were issued in several areas, including instructions defining costs of union-related activities which may be recognized in Medicare reimbursement and those which may not; instructions on reimbursement for inpatient and long-term care services furnished by swing-bed hospitals; and instructions intended to eliminate excessive payments for long-term rental of durable medical equipment when purchase would be more economical. Implementing provisions of DEFRA, instructions were published providing for Part B coverage of blood clotting factors (and items related to their administration) for hemophilia patients competent to use them without medical supervision, and providing for special enrollment and premium consideration for persons 65 through 69 years old who delayed or terminated Part B enrollment because they were covered under the working aged provision.

Guidelines were issued to implement the DEFRA requirement for use of carrierwide fee schedules for clinical diagnostic laboratory tests performed in a physician's office, an independent laboratory, or a hospital laboratory for its outpatients.

DEFRA established a 15-month freeze on Medicare reimbursement for physician services and created a physician participation program. HCFA developed physician participation agreement forms, explanatory fact sheets, and covering letters for carriers to release to physicians in late August 1984. HCFA also issued guidelines to carriers for processing the agreements and handling claims from participating physicians.

Instructions were issued to establish readability standards for Part B review determination letters and to preclude a Part A provider from representing a beneficiary in the Part

A appeals process. Other initiatives were concerned with provider reimbursement appeals and disclosure without beneficiary consent of identifiable information under certain circumstances.

Finally, in 1984, HCFA began a feasibility study of Medicare coverage of heart transplantation.

HIGHLIGHTS OF THE DEFICIT REDUCTION ACT OF 1984

During FY 84, Congress passed one major bill that affected the Medicare program. The Deficit Reduction Act of 1984 requires a reduction in Medicare program expenditures of $6.8 billion over fiscal years 1984-87, largely through reimbursement limitations affecting providers. The significant provisions of the measure barred for 15 months, beginning July 1, 1984, increases in the amount the Medicare program reimbursed doctors for services performed for beneficiaries and imposed stiff penalties for doctors who treated Medicare patients but did not abide by the freeze; maintained the amount of the Part B premium at 25 percent of program costs for 2 calendar years; and established fee schedules for outpatient diagnostic laboratory tests.

Additional provisions of the law authorized rural hospitals with urban characteristics to apply for status as rural referral centers; curtailed the reevaluation of assets to protect Medicare against unwarranted cost increases where providers change ownership through merger or acquisition; and required employers to offer group health insurance to workers under age 65 whose spouses aged 65 to 70 were entitled to Medicare, thus making Medicare secondary payer for such spouses.

REPORT ON RESEARCH, DEMONSTRATIONS, AND EVALUATIONS

Research and demonstrations in support of the Medicare program are authorized in the Social Security Act and the Social Security Amendments of 1967, 1972, and 1983.

HCFA's Office of Research and Demonstrations (ORD) undertakes studies and demonstrations to develop ways to promote efficiency and quality in Medicare and other HCFA programs. It assesses the impact of the programs on health care costs, program expenditures, beneficiary access to services, health care providers, and the health care industry. These research and demonstration projects also test and evaluate alternatives to present reimbursement, coverage, eligibility, and management policies of the Medicare program.

During FY 84, HCFA conducted research, demonstration, and evaluation projects in seven program areas: hospital payment, physician payment, long-term care, alternative payment systems, program analysis and evaluation, coverage, and prevention.

END-STAGE RENAL DISEASE (ESRD) PROGRAM

The ESRD program continued to show increases in the numbers of people receiving dialysis and kidney transplants and in total expenditures for services. During a 12-month period, the total dialysis population grew by 9 percent, from 71,987 to 78,483. The number of transplants rose to 6,968 from 6,112 in 1983, a 14 percent increase. Total expenditures for ESRD services were $1.9 billion, up from $1.8 billion; the total is likely to increase as more bills are posted. Most encouraging, however, was the 11.7 percent increase in the home dialysis population. Because it is less costly than infacility dialysis, home dialysis, as its use increases, holds the promise of helping to contain the growing costs of this program.

VALIDATION SURVEYS OF HOSPITALS ACCREDITED BY THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS

The purpose of the Medicare validation program is to determine the effectiveness of the JCAH accreditation process in providing reasonable assurance that hospitals comply with the intent of the Medicare Conditions of Participation. Each year, a statistical sample of the approximately 5,100 JCAH-accredited hospitals is selected for validation surveys. Under contract with the Secretary, State agencies (SAs) conducted 46 validation surveys during FY 84.

In addition to the sample hospitals, an accredited hospital is subject to an SA survey when there is an allegation that significant deficiencies threaten the health and safety of patients. Allegation surveys evaluate only the specified condition(s), as authorized by HCFA's regional offices. If a significant deficiency is found in the specified condition(s), the investigation is expanded to a full survey. For this report period, 167 hospitals received allegation investigations. Sixteen percent (26 of 167) were found out of compliance with one or more conditions.

In both sample and allegation surveys, if significant deficiencies are found, the hospital is placed under SA surveillance until the deficiencies are corrected. The hospital is no longer deemed to meet Medicare Conditions of Participation and the SA monitors the correction of any deficiency as if the hospital were unaccredited.

In FY 84, HCFA's validation analysis was conducted in two areas: Life Safety Code (LSC) and General Health and Safety requirements. The LSC of the National Fire Protection Association is a consensus standard adopted by reference in Federal regulations that provides a reasonable level of safety from fire and emergencies. During FY 84, 74 percent (34 of 46) of validated hospitals were in compliance with the LSC.

During this report period, Medicare found 80 percent (37 of 46) of JCAH-accredited hospitals receiving validation surveys in compliance with general health and safety

conditions. With respect to the general health and safety conditions for validated hospitals, the nursing and laboratory conditions were most frequently found out of compliance.

MEDIGAP

HCFA continued to monitor the compliance of applicable State statutes and regulations with the minimum standards contained in the Federal Medigap law. These standards, developed by the National Association of Insurance Commissioners and incorporated into the Federal statute, are designed to provide minimum benefits and protections for individuals who wish to purchase private health insurance to supplement their Medicare coverage.

In addition, the Federal law provides criminal penalties for certain fraudulent or abusive marketing practices. HCFA screens complaints received from consumer organizations, individuals, and other Government agencies and refers actionable cases to the Office of the Inspector General or to State insurance departments for investigation and prosecution.

In FY 84, HCFA was informed of 22 possible violations of the penalty provisions. Of these, 5 were investigated by specific State insurance departments, 15 were closed by HCFA for lack of evidence, and 2 were investigated by the Office of the Inspector General.

CHAPTER I. PROGRAM OPERATIONS

BENEFICIARIES

As of July 1, 1984, the following beneficiaries had coverage under Medicare:

Beneficiaries	Number
Aged	27.6 million
Disabled	2.9 million
Total	30.5 million
Part A Beneficiaries	30.0 million
Part B Beneficiaries	29.4 million

Of beneficiaries age 65 and over, 95 percent were covered by both Part A (hospital insurance) and Part B (supplementary medical insurance), while 92 percent of all disabled beneficiaries were covered by both parts.

The number of aged persons entitled to Medicare, as of July 1984, increased nearly 462,500 (from 27.1 million to 27.6 million) over the previous annual enrollment. This 1.7 percent net increase of Medicare aged enrollment is below the annual net growth of over 2 percent in the segment of the U.S. population age 65 and over in each of the last 10 years. The average age of beneficiaries also increased. For example, the proportion of very aged beneficiaries (age 85 and over) has increased from 7 percent in 1970 to 10 percent in 1984. Finally, there has been a 13 percent decline in the death rate of the 65-and-older group since 1970. The death rate in 1970 was 5,892 per 100,000, as compared to 5,114 in 1984. These factors contribute to more intensive use of Medicare-covered health care services over a longer period of time.

HEALTH CARE RESOURCES

As of July 1, 1984, 6,675 hospitals, with 1,144,142 beds, were participating in Medicare, compared to 6,737 hospitals with 1,143,699 beds in 1983. The participating hospitals included 6,038 short-stay hospitals, 433 psychiatric institutions, and 204 other long-stay institutions. Of the total number of beds, 89 percent were in short-stay hospitals, 9 percent in psychiatric institutions, and 2 percent in other long-stay facilities.

As of July 1, 1984, there were 5,952 skilled nursing facilities (SNFs) with 530,403 beds participating in Medicare, up from 5,632 facilities with 511,663 beds during the prior year. Participating facilities included skilled nursing facilities, separately organized extended-care units in hospitals, and some separate skilled nursing units connected with residual homes for the aged.

The number of home health agencies (HHAs) participating in the Medicare program rose from 3,959 to 4,684.

A total of 3,801 independent laboratories had been approved for Medicare reimbursement, up from 3,643 a year earlier.

There were 1,368 facilities or units providing services to program beneficiaries requiring maintenance dialysis or kidney transplants.

In addition, as of July 1, 1984, 420 rural health clinics, 155 ambulatory surgical centers, and 132 hospices were certified to participate in Medicare.

BENEFIT PAYMENTS

During FY 84, Medicare paid $41.5 billion hospital insurance benefits (Part A) and $19.5 billion medical insurance benefits (Part B). These amounts represent an increase of 9.6 percent over payments of $38.1 billion and $17.5 billion, respectively, during the preceding year. Almost all of the increase resulted from increases in hospital costs and higher physician fees recognized by the program. Studies discussed in Chapter V indicate that price inflation contributes most to these increases. The remainder of the increase in benefit payments was due to such factors as utilization of more expensive technology in health care delivery, increasing rates of utilization of services, and increases in both the number of aged beneficiaries and the proportion of persons aged 75 or older within the aged population. The older beneficiaries require more medical services and more frequent hospitalization for longer stays.

In FY 84, approximately 100 million inpatient hospital days were approved for payment. The aged accounted for 88 percent of the total, while the remaining 12 percent was for the disabled. The rate of covered days of care per 1,000 enrollees was about 3,300 for the aged and 4,000 for the disabled. In FY 84, hospitals were paid $39 billion for Part A benefits, 94 percent of all Part A payments. The program also covers convalescent care after a hospital stay of at least 3 days, either by transfer to a skilled nursing facility or through home health services. Benefit payments for these two levels of extended-care services represented 6 percent of total Part A payments.

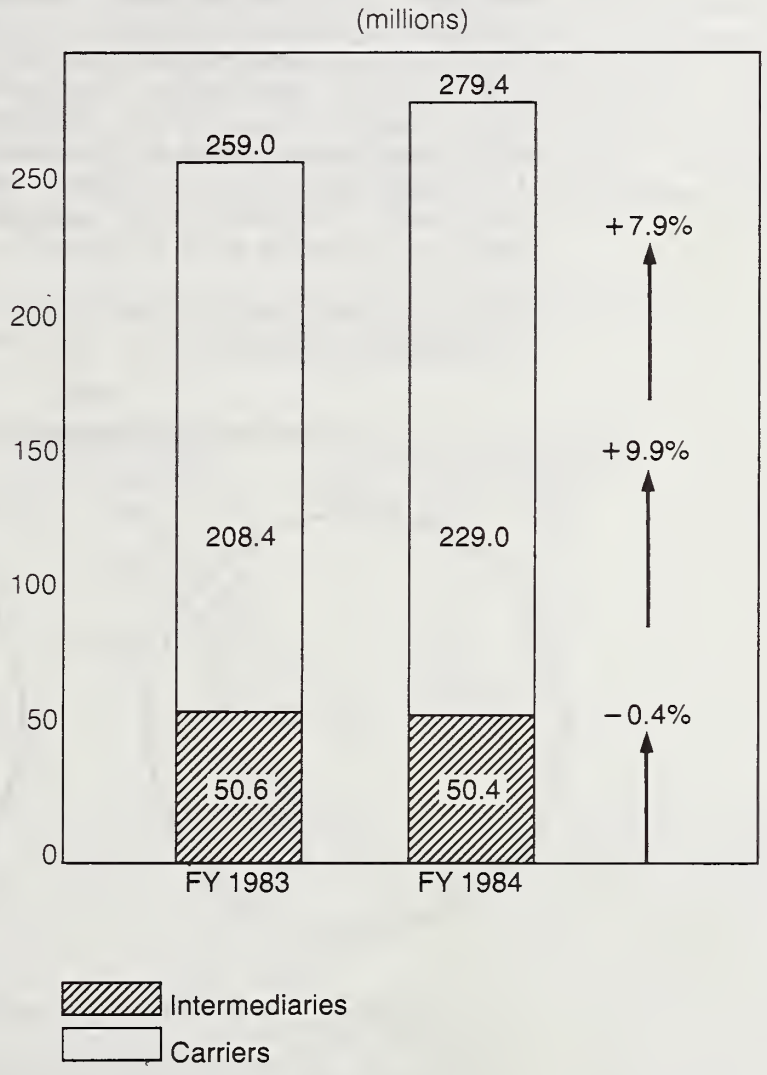
Medical insurance payments for physician (excluding inpatient radiology and pathology services) and supplier services accounted for 74 percent of Part B payments. The next highest payments were for outpatient services (19 percent), followed by inpatient services furnished by radiologists and pathologists (3 percent), group practice prepayment plans (3 percent), and laboratory services (1 percent). A relatively small amount was paid under Part B for home health services (0.1 percent).

CLAIMS PROCESSING PERFORMANCE

Intermediaries received 50.4 million claims in FY 84, a decrease of 0.4 percent below FY 83. Claims received by carriers rose at a rate of 9.9 percent, to a total of 229.0 million. Overall, the volume of Medicare claims rose 7.9 percent, to 279.4 million. Figure 1 compares the claims received by contractors in FY 83 and FY 84.

Figure 1

CLAIMS RECEIVED BY MEDICARE CONTRACTORS



DISTRIBUTION OF CLAIMS

The majority of claims received by intermediaries during FY 84 were requests for payment for outpatient services provided Medicare beneficiaries. These claims accounted for 58.9 percent of intermediaries' claims. Inpatient hospital claims accounted for 24.1 percent of claims received, while

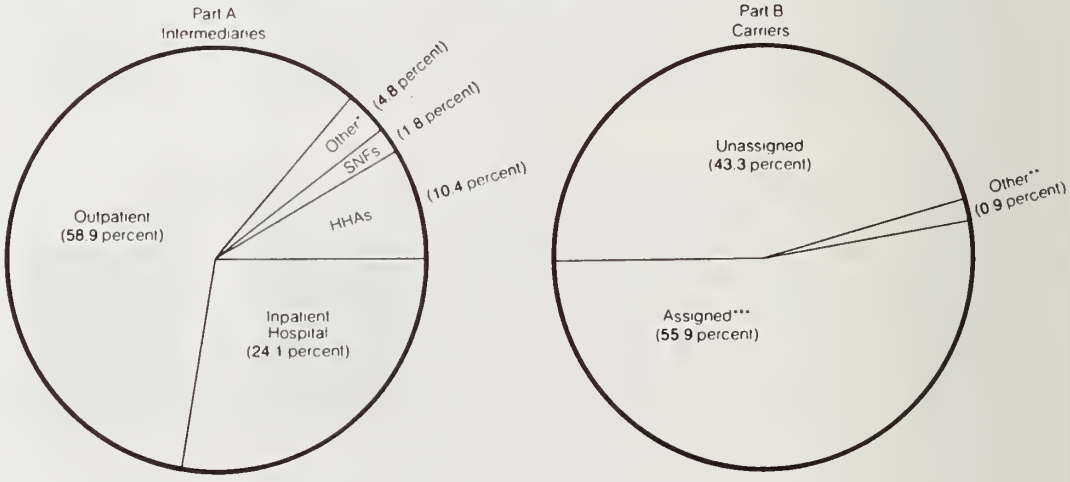
HHA and SNF claims accounted for 10.4 percent and 1.8 percent, respectively. The remaining 4.8 percent were claims submitted for ancillary and other miscellaneous services payable under Part B.

The distribution of claims received by carriers changed slightly from FY 83 to FY 84. The percentage of claims submitted by physicians and suppliers on assignment increased from 51.0 to 55.9 percent. In contrast, the percentage of claims submitted unassigned by beneficiaries dropped slightly, from 44.3 to 43.3 percent, while those submitted by provider-based physicians and group practice prepayment plans fell sharply, from 4.8 to 0.9 percent. This latter change was due to the elimination of the HCFA-1554 billing option for hospital-based physicians. Services provided on or after October 1, 1983, by hospital-based physicians must be billed for in the same way as all other physician services, with the same option for assignment. The percent of assigned claims to total claims showed an increase of 4.9 percent.

Figure 2 shows the distribution of FY 84 receipts by type of claim for intermediaries and carriers.

Figure 2

DISTRIBUTION OF FY 84 RECEIPTS BY TYPE OF CLAIM



* Ancillary and other miscellaneous services payable under Part B.

** Claims for services provided by provider-based physicians and group practice prepayment plans, who do not bill patients directly.

*** This represents the assignment rate measured against all claims. When measured only against claims in which patients are billed directly (i.e., excluding the 0.9 percent of claims for provider-based physician services and group practice prepayment plan services), the assignment rate in FY 84 was 56.4 percent, the figure usually quoted as the Medicare assignment rate. This is a 5.4 percent increase over the FY 83 assignment rate of 53.5 percent.

CLAIMS PROCESSING TIMELINESS

Timeliness measures of contractor claims processing performance in FY 84 indicated an overall decline for both intermediaries and carriers. (It should be noted that HCFA anticipates a change in the method for calculating processing times for future years.)

The average processing time for intermediaries increased from 7.0 days to 8.4 days, and the average monthly percentage of bills pending over 30 days increased from 11.6 percent to 15.0 percent. (See Table 1.) There were several reasons for this deterioration: further implementation of the prospective payment system, development of Medicare secondary payer (MSP) bills, implementation of UB82, consolidation of several contractor operations, new bill processing systems at several contractors, and changes in the method of reimbursement for independent laboratory services.

Table 1. Claims Processing Timeliness for Intermediaries

Quarter	Contractor Processing Time (Mean Days) FY 83	FY 84	Percent of Claims Pending Over 30 Days FY 83	FY 84
1	6.9	7.3	12.2	15.8
2	7.5	9.3	10.9	14.5
3	6.6	8.4	10.6	14.4
4	7.0	8.7	12.8	15.2
Yearly Average	7.0	8.4	11.6	15.0

Carriers showed an increase in yearly average claims processing time from 9.9 days to 11.5 days. Over the same time period, the monthly percentage of claims pending over 30 days for carriers increased from 9.0 percent to 12.1 percent. (See Table 2.) As was the case for intermediaries, there were several reasons for this decline: development of Medicare secondary payer claims, changes in billing methods for hospital-based physician claims, implementation of HCFA Common Procedure Codes (HCPCs) (i.e., changes in coding requirements), new claims processing systems at several contractors, and changes in the method of reimbursement for independent laboratory services.

Table 2. Claims Processing Timeliness for Carriers

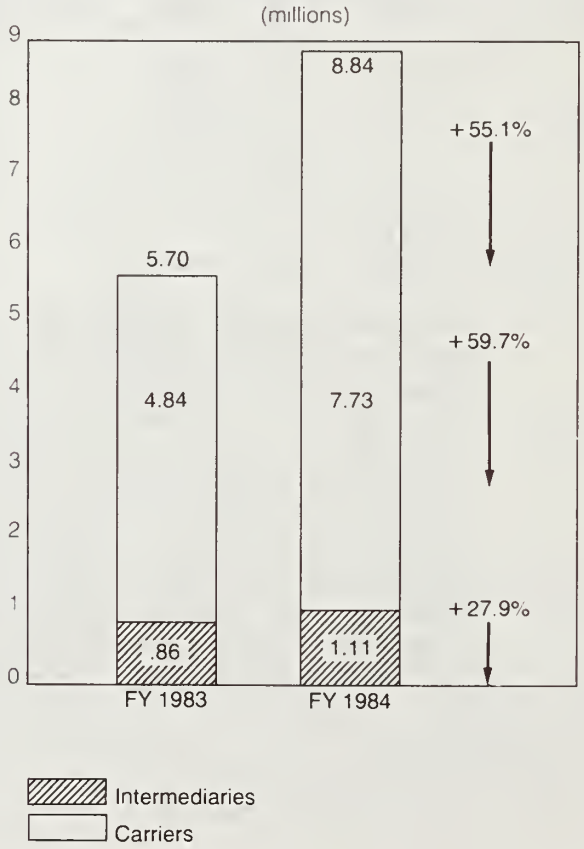
Quarter	Contractor Processing Time (Mean Days) FY 83	FY 84	Percent of Claims Pending Over 30 Days FY 83	FY 84
1	9.0	9.9	9.4	11.4
2	10.8	12.1	8.3	11.8
3	9.4	11.0	8.2	11.9
4	10.4	12.9	10.2	13.1
Yearly Average	9.9	11.5	9.0	12.1

CLAIMS PENDING

Because of the problems mentioned under "Claims Processing Timeliness," both intermediaries and carriers experienced increases in the volume of pending claims during FY 84. Pending claims rose 27.9 percent for intermediaries and 59.7 percent for carriers. (See Figure 3.)

Figure 3

CLAIMS PENDING FOR MEDICARE CONTRACTORS



CONTRACTOR ADMINISTRATIVE COST EXPERIENCE

The FY 84 intermediary processed workload increased 3.1 percent over the previous fiscal year, whereas total cost (excluding audit) increased 13.1 percent. This increase was due to increased payment safeguards and productivity investment efforts. Person-years for operations (excluding audit) increased 12.1 percent and resulted in a decrease in productivity per productive hour.

The unit cost for all operations (including audit) increased 51 cents, and the unit cost for operations excluding audit increased 34 cents. The difference reflects an increase of 12.7 percent in audit costs. Table 3 summarizes intermediary cost experience.

Table 3. Intermediary Administrative Costs, FY 83 and FY 84

	FY 83	FY 84	Net Change	Percent Change
Workload Processed	$ 48,688,877	$ 50,215,984	$ 1,527,107	3.1
Total Cost	261,824,227	295,691,780	33,867,553	12.9
Provider Audit Cost	87,993,831	99,142,214	11,148,383	12.7
Total Cost (Ex. Audit)	$173,830,396	$196,549,566	$22,719,170	13.1
Unit Cost	$ 5.38	$ 5.89	$ .51	9.5
Unit Cost (Ex. Audit)	3.57	3.91	.34	9.5

For carriers, the unit cost decreased by 8 cents during FY 1984. This reflects a workload increase of 10.1 percent and total cost increase of 6.2 percent. Productivity increased 2.1 percent, while the personal service cost per productive hour increased by 3.1 percent. Table 4 summarizes the administrative cost experience of carriers.

Table 4. Carrier Administrative Costs, FY 83 and FY 84

	FY 83	FY 84	Net Change	Percent Change
Workload Processed	$204,048,829	$224,676,923	$20,628,094	10.1
Total Cost	485,833,257	515,833,214	29,999,957	6.2
Unit Cost	$ 2.38	$ 2.30	$ (.08)	(3.4)

CONTRACTOR PERFORMANCE

Essentially, beneficiaries and the health community, as well as the public at large, judge the performance of Medicare by the performance of intermediaries and carriers.

Contractors' effectiveness in processing claims, in communicating program policies and procedures to the public, and in establishing relationships with the health community shapes the public and professional response to the program.

In FY 84, HCFA evaluated the performance of Medicare contractors by using the Contractor Performance Evaluation Program (CPEP). The CPEP is comprised of pre-established performance criteria and standards with specific acceptance quality levels designated for each discrete area of performance measured. The CPEP is divided into two parts: Part A CPEP is applicable to intermediaries; Part B CPEP is applicable to carriers. The criteria and standards are applied to contractors as uniformly as possible.

The process of applying standards and criteria was mandated by the Medicare and Medicaid Fraudulent Practices Act (Public Law 95-142). Performance measures were first applied to intermediaries for FY 80 and to carriers for FY 81. Each subsequent fiscal year, the criteria and standards are revised and refined to more accurately measure contractor performance.

The CPEP is implemented by HCFA's 10 regional offices. Throughout the fiscal year, the regional staffs evaluate contractor performance by conducting onsite reviews and analyzing performance data as required in the CPEP. At the end of the year, the regions prepare and publish Annual Contractor Evaluation Reports (ACERs) for each contractor in their service area.

HCFA uses the results of the application of CPEP criteria and standards as the major factor in contract management. When combined with historical perspective, this process has proved to be an effective tool for identifying patterns of contractor performance. Establishing performance goals and monitoring and evaluating systems has achieved overall improvement in contractor operations.

In FY 84, the Part A CPEP measured performance in the following major areas: bill processing, provider reimbursement, contract management, prospective payment-medical review, and prospective payment base-year audit. The last two areas were added as a result of passage of the legislation creating the prospective payment system. This new approach to making payment for hospital care created substantially revised audit activities. The change in peer review organizations demanded substantially increased medical review activities. In addition, statistical standards for unit cost of bill processing and timeliness of bill processing were established.

The Part B CPEP measured performance in the following major areas: claims processing, program payment, and contract management. The Part B statistical standards were unit cost of claims processing, timeliness of claims processing, and quality of claims processing.

The CPEP also reflected HCFA's renewed emphasis on controlling benefit payments, reducing administrative costs, and assuring that contractors do not compromise the quality of their work to achieve savings. Review areas were augmented and acceptable quality levels were increased.

PREPAYMENT PLANS

Health maintenance organizations (HMOs) are continuing to increase in number as an alternative to traditional forms of health care delivery. An HMO is an organization which provides its members comprehensive health services, without regard to frequency or extent of services, in return for predetermined, fixed premiums paid by members. The Medicare program has been contracting with risk and cost HMOs since 1972. During 1984, 28 HMOs signed contracts to enroll Medicare members. This raised the number of contracting HMOs (risk and cost) by 37 percent, from 75 to 103. Medicare membership in HMOs increased 92 percent, from 184,093 to 354,198. Total payments to contracting HMOs more than doubled (from $245 million to $492 million) from the preceding year.

Public Law 97-248, the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), expanded the definition of organizations eligible to enter into Medicare HMO contracts to include competitive medical plans (CMPs). The old risk contract option was replaced by prospective payment under risk-sharing contracts with HMOs and CMPs at a rate equal to 95 percent of the adjusted average per capita cost (AAPCC). The cost contract option remains. The change in definition of risk contracting is expected to increase greatly the rate of HMO contracting.

QUALITY AND APPROPRIATENESS OF CARE

A major goal of the Medicare program is to assure that its beneficiaries receive appropriate health care services. This is accomplished by requiring that facilities caring for Medicare beneficiaries be structurally safe, clean, properly staffed, and provide needed services, and that the actual care delivered to beneficiaries meet accepted professional standards. In addition to assuring the quality of service received, the Health Care Financing Administration (HCFA) must make sure that services are necessary and are performed at the most economical level consistent with accepted standards of care.

MEDICAL REVIEW IN HOSPITALS

TEFRA, through the Peer Review Improvement Act of 1982, required HCFA to contract with private utilization and quality control peer review organizations (PROs) to determine the medical necessity, appropriateness, and quality of services provided under the Medicare program. Administrative decisions were made to limit this review authority initially to inpatient hospital care. The PRO program will be fully implemented during FY 1985. Prior to implementation of the PRO program, review of inpatient medical services required by the prospective payment system (PPS) was carried out by Medicare fiscal intermediaries (FIs) and professional standards review organizations (PSROs).

The emphasis of medical review of inpatient hospital care (whether by PROs, PSROs, or FIs) was on the prevention of "gaming" of the prospective payment system. Congress specified that medical review under PPS would focus on five basic issues:

- Reducing unnecessary and inappropriate hospital admissions;
- Validating the accuracy of the diagnosis and procedure codes assigned by the provider to determine payment;
- Assuring that the quality of patient care conformed to professional standards;
- Reducing unnecessary and inappropriate continued stays for day-outlier cases; and
- Reviewing cost-outlier services to determine if they were medically necessary, reasonable, and appropriately billed.

PRO required review activities during FY 84 were:

- Preadmission review of every elective case for at least five specified procedures or diagnoses selected by the PRO. This review allowed PROs to ensure the necessity of admissions for procedures that could, in many cases, be done safely and effectively on an outpatient basis.
- Review of admissions occurring within 7 days of a discharge. This allowed PROs to identify any situations in which readmissions could be caused by premature discharge or poor-quality care during the initial admission.
- Review of every permanent cardiac pacemaker implantation, because of congressional concerns about overutilization of such procedures.
- Review of transfers from a PPS hospital to another hospital or to a PPS-exempt psychiatric, rehabilitation, or alcohol detoxification unit, or to a swing bed within the same hospital, to make sure that the transfer was medically justified.
- Review of admissions and days of care in specialty hospitals and distinct-part psychiatric, alcohol detoxification, and rehabilitation units.
- Review of every 20th admission not otherwise reviewed, as an overall check on the necessity of admissions.

- Review and validation of diagnostic and procedural information supplied by hospitals, and review of every case involving a day or cost outlier.

PROs were also required to propose and achieve admission objectives to:

- Reduce admissions for procedures that could be performed effectively and with adequate assurance of patient safety in an ambulatory surgical setting or on an outpatient basis.

- Reduce the number of inappropriate or unnecessary admissions or invasive procedures for specific diagnosis-related groups (DRGs).

- Reduce the number of inappropriate or unnecessary admissions or invasive procedures by specific practitioners or in specific hospitals.

In addition, PROs were required to achieve significant improvement in the quality of patient care by achieving quality objectives to:

- Reduce unnecessary hospital readmissions resulting from substandard care provided during the prior admission.

- Assure the provision of medical services which, when not performed, have significant potential for causing serious patient complications.

- Reduce the risk of mortality associated with selected procedures and/or conditions requiring hospitalization.

- Reduce unnecessary surgery or other invasive procedures.

- Reduce avoidable postoperative or other complications.

Since PRO contracts are for a period of 2 years, results of these activities are not available at this time. These results will be outlined in a future PRO annual report to Congress.

MEDICAL REVIEW OF PART B SERVICES

Part B medical review used a two-tiered approach to assure that Medicare payment was made only for medically necessary, covered services. One approach was the continued use by carriers of computerized prepayment utilization screens to identify potentially noncovered services. Some of these screens result in the automatic denial of items excluded

from Medicare coverage, while other screens result in the claim's being suspended from the claims processing system for review before payment is made.

Carriers used a variety of prepayment screens. HCFA staff analyzed the cost-effectiveness of these screens in an effort to determine which had the most potential for use by all carriers across the country. This analysis will enable HCFA to require all carriers to use several prepayment screens in the future.

The second approach to Part B medical review was the postpayment review process. This is a statistical analysis that makes it possible for carriers to identify potentially fraudulent or abusive practices requiring investigation and followup through:

- Monitoring physicians' claims experience;
- Identifying physicians with aberrant utilization patterns; and
- Targeting review on aberrations.

In addition, postpayment review identifies the need for new or modified prepayment screens: One set of prepayment screens is developed on the basis of postpayment review findings, enabling carriers to examine questionable or potentially abusive situations before payment is made.

MEDICAL REVIEW OF OTHER THAN INPATIENT HOSPITAL SERVICES

The first HCFA directives for FI medical review and associated reporting requirements were established this year. FIs were required to review 100 percent of admissions to hospital-based skilled nursing facilities (SNFs) from PPS hospitals and 30 percent of admissions to freestanding SNFs from PPS hospitals. The purpose of this review was to address concerns that PPS hospitals might be discharging patients to SNFs before they were well enough.

FIs were also required to review 100 percent of hospice claims during 1984 to assure that payment to this new provider type was made only for medically necessary, covered services.

FIs continued to review home health claims and outpatient claims under their individual medical review procedures, in accordance with broad HCFA policy directives.

STANDARDS AND CERTIFICATION

Medicare requires that participating facilities be structurally safe, clean, properly staffed, and provide needed

services and that the care provided meet accepted professional standards. To participate in the Medicare program, health care facilities must meet conditions of participation which specifically define those health and safety standards. To ensure that those standards are met, States conduct surveys under contract with the Department. Because hospitals that are accredited by the Joint Commission on Accreditation of Hospitals (JCAH) or the American Osteopathic Association (AOA) are deemed to meet Medicare requirements, States survey only hospitals that are not accredited by JCAH or AOA. On a sample basis, however, States survey JCAH and AOA hospitals to validate that they continue to meet Medicare requirements. (For a complete report on the validation process, see Chapter VIII of this report.)

SECOND SURGICAL OPINION PROGRAM

Encouraging patients to obtain second opinions before undergoing nonemergency surgery has reduced the incidence of inappropriate surgery. Launched in 1978 with a major publicity campaign, this "second-opinion program" is premised on the patient's right to know the benefits and risks of recommended surgery and any alternatives to surgery.

The program was given added impetus in 1984 by the distribution of 9 million brochures entitled "Thinking of Having Surgery? Think About Getting A Second Opinion." In addition, public service announcements promoting the program and publicizing the national toll-free number were distributed to 730 television stations and over 6,000 radio stations. Approximately 76,000 calls have been made to the national hot line since the program began.

IMPROVING UTILIZATION SAFEGUARDS

Part of the increasing costs of Medicare continues to be attributable to the furnishing of services that either are not medically necessary or are provided at an inappropriate level. Medical care is particularly vulnerable to excessive and inappropriate use because the decisions which must be made are often subjective. In addition, some medical practices that tend to induce overutilization have become traditional in the American health care delivery system. One of the most obvious examples of overutilization is unnecessary occupancy of expensive hospital beds when outpatient care or care in a skilled nursing facility or on an outpatient basis would be more appropriate.

The structure of the program provides some fundamental controls on utilization. Benefit limitations, for example, assure coverage for the vast majority of medical situations yet provide upper limits beyond which payment will not be

made. Deductible and coinsurance amounts require patients to share the cost of services and thus provide some motivation not to seek or prolong services unnecessarily. Requirements that services be furnished on a physician's order and that a physician certify that they are medically necessary also help control use of services.

During 1984, HCFA continued to refine prepayment screens used to identify potential overutilization or variations from medical-necessity norms. A particularly important screen permits prompt identification of physicians whose total bills in given periods significantly exceed what would be expected in ordinary practice. Other screens help identify physician-patient contacts that appear abnormally frequent for a particular diagnostic or therapeutic category and potential markup situations where physicians add a charge for services actually provided by an independent laboratory. Although the facts of a case often justify variations from usual patterns, identifying such variations in the claims review process is indispensable to isolating instances of truly improper utilization.

BENEFICIARY SERVICES

An integral part of the Agency's success in administering the Medicare program is to inform and educate beneficiaries about HCFA programs and services available to them. This is accomplished through written communications such as pamphlets, handbooks, and brochures, and through open channels of communication with beneficiary representation groups.

During FY 84, several initiatives were undertaken:

- Enhancement of the Medigap education program--HCFA sponsored training sessions through the regional offices, reaching beneficiaries in 50 States.

- Publication and distribution of "Medicare/Medicaid Notes"--This fact sheet of current changes in Medicare and Medicaid policy was distributed to 40 national beneficiary organizations which have publications for their members.

- Liaison with beneficiary organizations--HCFA representatives attended over 60 national organization conferences and meetings and participated in workshops, panel discussions, and forums on Medicare-related issues:

QUALITY CONTROL PROGRAMS

HFCA monitors the quality of Medicare program administration through an array of payment review and other programs.

HOSPITAL/REIMBURSEMENT REVIEW PROGRAM (HOSP-RRP) AND HOME HEALTH AGENCY REIMBURSEMENT REVIEW PROGRAM (HHA-RRP)

The HOSP-RRP and HHA-RRP are comprehensive programs designed to evaluate the quality of the settlement of provider cost reports by Medicare intermediaries. Evaluation results are incorporated in the Contractor Performance Evaluation Program (CPEP). This is the only evaluative measure included under intermediary audit and reimbursement functions.

In 1984, 31 intermediaries were evaluated under the HOSP-RRP, and 33 intermediaries were evaluated under the HHA-RRP. A total of 98 hospital providers were reviewed, and the total number of HHA providers reviewed was 61. Total estimated dollar recoveries amounted to $7.1 million.

INTERIM PAYMENT REVIEW PROGRAM (IPRP)

The IPRP is designed to monitor intermediaries' performance in calculating and adjusting the PPS interim rates and computations of payment on individual bills for hospitals. Their performance is evaluated through a review of PPS interim rate calculations and bill payment computations.

During 1984, a sample of 520 hospitals was reviewed to verify the computation of interim rate reimbursement for:

- Part A inpatient operating costs.
- Capital-related costs.
- Direct medical-education costs.
- Kidney acquisition costs.
- Medicare-allowable bad debts.
- Return on equity capital for proprietary providers.
- Indirect costs of medical education.

In addition, a sample of 3,271 Medicare bills was reviewed to verify computations of payment amounts.

The reviews identified erroneous interim payment amounts of approximately $11.9 million ($11.1 million in erroneous interim overpayments to the providers and $0.8 million in erroneous underpayments).

MEDICARE PART B QUALITY ASSURANCE PROGRAM

The Part B Quality Assurance program was designed to provide a statistically valid and objective procedure for evaluating carrier claims-processing performance. The data generated constitute an integral part of the CPEP, which is a primary mechanism for determining carrier contract renewal, discontinuance, or required program improvements. A national quarterly report is published that ranks carriers based on the cumulative error rates assessed during the most recent 12-month period. Carriers are ranked both on occurrence error rate (processing errors per 100 line items in the universe) and on payment/deductible error rate (dollar errors per $100 of submitted charges in the universe). A penalty figure is included in the payment/deductible error rate when a carrier fails to review all sample claims selected.

For FY 84, results showed that 36 Medicare Part B carriers (49 processing sites) processed 214 million claims with submitted charges totaling $29 billion. Normally, 39 carriers (53 processing sites) operate Medicare Part B, but not all carriers submitted data in a timely fashion. Carrier occurrence error rates ranged from 1.9 to 14.0. The mean occurrence error rate was 6.4. Carrier payment/deductible error rates ranged from 0.4 to 4.0, with a mean rate of 1.8.

Payment/deductible dollar errors (representing overpayments, underpayments, and misapplication of the deductible) plus penalty totaled $522 million. The total payment/deductible error rate with penalty increased from 1.5 percent in FY 83 to 1.8 percent in FY 84. The national overpayment error rate, based on 49 of 53 carrier locations reporting, was 1.00. This indicates that $1.00 was estimated to be overpaid per $100 of submitted charges.

TARGET RATE IMPLEMENTATION MONITORING (TRIM) PROGRAM AND HOME OFFICE (HO-TRIM) PROGRAM

The TRIM program is a review program designed to monitor concurrently the quality of the base-year audits and computations of the target amount per discharge under the prospective payment system. The evaluation of the intermediaries' performance will be accomplished through a review of the crucial phases of the target-amount-per-discharge (rate) determination process: preaudit, audit, rate calculation, and rate notification.

The HO-TRIM program is designed for regional office use in concurrent monitoring of the quality of chain home office base-period cost statements. The HO-TRIM program also

monitors the timely issuance by the designated intermediary of the home office cost notification(s) to local intermediaries.

In FY 84, a total of 503 hospitals and 38 home office base-period audits were reviewed. The total estimated dollar adjustments identified were $28.1 million. The adjustments consisted of $26.0 million of provider overpayments and $2.1 million of provider underpayments.

OPERATIONAL REVIEWS

Operational reviews assess the need for policy and operational reforms in vulnerable program areas. To inform HCFA senior management of the financial and operational implications of policy and management decisions, HCFA staff perform studies of selected program and policy issues through extensive research of inhouse information supplemented by additional documentation and onsite review.

The following sections discuss operational reviews undertaken in FY 84.

HOME HEALTH SERVICES

A comprehensive study of home health services or agencies was conducted. The review examined 1,025 beneficiary records from 39 home health agencies (HHAs). The study also included an analysis of fiscal intermediary claims-processing decisions and home visits to 211 beneficiaries. The objectives of the study were to:

- Measure the accuracy of coverage determinations made by HCFA's fiscal intermediaries.
- Assess the effectiveness of HCFA's Home Health Coverage Compliance Review Program (CCRP).
- Identify the major factors contributing to the growth of the home health industry.
- Evaluate the impact of the hospital prospective payment system on home health agencies existing prior to PPS.

The study found that one-third of all home health care billed to Medicare in FY 84 was for noncovered services. Fiscal intermediaries denied less than 3 percent of home health care services billed. The major cause of the low FI denial rate for these claims is that the medical information submitted on or with the claims is generally not adequate to make appropriate coverage determinations. The study also found that CCRP results in a higher denial rate than the normal claims processing/utilization control systems used by fiscal intermediaries.

The number of Medicare-certified HHAs, particularly proprietary and provider-based, has increased dramatically in the 4 years since 1980. The increase is due to several factors, including Federal legislation, sociocultural influences, changes in medical technology, and State-level factors such as waiver status, licensure, and certificates of need.

There was evidence of good-quality care and some evidence of poor-quality care. It was subsequently determined that there were inadequate controls to ensure quality HHA services.

Data available at the time of the study indicated that there had not been a significant change in PPS hospital discharges to HHAs or in the number of services provided to HHA patients since the start of PPS.

As a result of the study, HCFA implemented a number of initiatives to improve the administration of the home health benefit. For example, the claims processing structure was realigned to make it more prescriptive and consistent; 10 fiscal intermediaries will service home health providers. The Coverage Compliance Review Program has been strengthened, and all HHAs are to use a minimum data set of information when adjudicating claims.

PARENTERAL/ENTERAL SERVICES

A study was undertaken to assess the appropriateness and effectiveness of HCFA coverage guidelines and to review carrier reimbursement practices for parenteral/enteral services. The study examined the medical and financial records of 1,241 beneficiaries who were receiving parenteral or enteral home nutrition and analyzed data from 13 carriers and 55 suppliers of parenteral and enteral nutrients.

The study found that all enteral nutrients supplied to the sampled beneficiaries were commercially prepared and could be purchased "over the counter." In all cases in the sample, the enteral nutrients could be purchased for less than the charges claimed by and reimbursed to the suppliers. Sixty-five percent of the enteral beneficiaries were using sophisticated pumps.

For parenteral beneficiaries, the study found a 25 percent difference in cost between patient-mixed and pharmacy-mixed nutrients.

The study also found that documentation requirements and reimbursement to suppliers varied significantly from carrier to carrier.

As a result of this study, coverage guidelines now state that medical justification is required for the use of pumps and that reimbursement will be based on the reasonable charge for the simplest model that meets the patient's needs. When pharmacy-mixed solutions are prescribed, the guidelines require that physicians document that parenteral patient-mixed solutions are not appropriate.

In addition, HCFA Common Procedure Codes (HCPCs) were developed and published in the Medicare Carriers Manual in October 1984. Finally, HCFA implemented a major change in processing Part B parenteral/enteral claims by switching from 55 carriers to a 2-specialty-carrier system.

PACEMAKER REPLACEMENTS

A review was initiated to identify the proportion of pacemaker replacements to all implants and the reason for replacing pacemakers, and to determine how often the replacement pacemakers were more sophisticated than the units replaced. The study looked at medical and financial records from 69 hospitals.

The study found that approximately 21 percent of all implants were replacements, and that more sophisticated replacements were implanted 58.5 percent of the time. The reasons for replacement were general failure (64.4 percent), a change in the patient's condition (17.2 percent), generator failure (9.4 percent), lead/electrode failure (6.3 percent), and manufacturer's recall (2.3 percent).

As a result of this study, HCFA performed audits at selected hospitals to study pacemaker warranties and recalls.

MEDICARE SECONDARY PAYER

The Medicare secondary payer (MSP) review included 50 hospitals and focused on their ability to identify MSP occurrence. Reviewers examined the degree to which hospitals were billing the primary insurer, with Medicare as the secondary payer.

The review found that hospitals generally identified MSP occurrences and possible primary insurers, but they generally did not use the MSP information and did not bill correctly (i.e., Medicare was being billed as the primary payer). The review also found that the actuarial projections for potential Medicare savings for the working aged were accurate.

As a result of the review, codes were inserted in the beneficiary master file to alert contractors of possible employer's group health plans. A CPEP evaluation element

was installed for use in 1985 that will focus on MSP savings by contractors, and a quarterly report of contractor MSP savings was established. In addition, a process was implemented to identify auto accident and other liability cases by editing trauma-related diagnosis codes.

SURVEY AND CERTIFICATION

A review of long-term care survey and certification was completed in August 1984. The review was designed to examine the problem of long-term care facilities that have remained in the Medicare and Medicaid programs despite consistent and recurring failure to meet certification requirements. A total of 126 facilities in 38 States were reviewed, and 73 State survey agencies completed questionnaires.

As a result of this study, HCFA's regional offices have been made aware of the characteristics of poor-performing long-term care facilities and are now in a better position to evaluate these facilities properly.

MEDICAL REVIEW/UTILIZATION REVIEW

A medical review/utilization review involving 15 carriers was conducted to determine and provide data on the most effective prepayment screens being utilized by carriers. The review examined cost effectiveness, commonalities, and appropriateness for national implementation. The information provided by this operational review resulted in the development and placement of a number of screens.

CHAPTER III. POLICY DEVELOPMENT

IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM

The Social Security Amendments of 1983 (Public Law 98-21) introduced one of the most sweeping changes in the Medicare program that had occurred since it began 19 years ago. It changed the method of payment for inpatient hospital services from the retrospective reasonable-cost basis to a prospective payment system (PPS) based on diagnosis-related groups (DRGs) applied at the time of a patient's discharge from the hospital. The new system is designed to reduce costs, provide greater predictability as to the amount of payment, and encourage greater efficiency and cost effectiveness in hospital operations.

Under PPS, each hospital is paid a predetermined, fixed rate for each Medicare inpatient discharge in accordance with a payment schedule for standard types of patient discharges. Each discharge is classified into one of 468 DRGs based on the patient's principal diagnosis, the presence of comorbid or complicating conditions, procedures performed, and the patient's age, sex, and discharge status.

Implementation of PPS began in 1984 and is to be phased in over 3 years. During the phase-in period, hospitals will be paid a blended PPS rate comprised of a Federal standardized portion (DRG) and a hospital-specific portion. Special adjustments are to be made for certain classes of hospitals. Provision is made for budget neutrality vis-a-vis the levels of payment mandated by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). The law also provides for rebundling nonphysician service costs into hospital inpatient costs where hospitals had previously allowed such services to be billed directly by outside suppliers.

Interim regulations were published on September 1, 1983, to permit implementation of PPS by the effective date of October 1, 1983. Final regulations followed on January 3, 1984.

Implementation has proceeded smoothly, with no significant problems or disruptions during the initial phase of the transition. As of September 30, 1984, 5,405 hospitals--81 percent of all Medicare hospitals--were participating under PPS.

REFINEMENTS TO PPS

After developing and implementing the major elements of the system, the Health Care Financing Administration (HCFA) began to refine it and correct inequities which had become apparent. Final regulations, issued on January 3, 1984:

- Assured full prospective payments to transferring hospitals for patients assigned to certain DRGs and when

patients were transferred to facilities excluded from PPS.

- Clarified the treatment of base-year costs and eliminated the reduction for outlier payments in the hospital-specific portion of the payment rate.

- Revised the criteria for special treatment of sole community hospitals (SCHs), cancer hospitals, and referral centers.

- Modified the definition of capital-related costs and the allowability of certain medical education costs as direct passthrough costs.

Public Law 98-369, the Deficit Reduction Act (DEFRA), which became law on July 18, 1984, contains additional provisions that affect rural referral centers, hospitals located in areas redesignated as rural, and hospitals located in urban areas that cross census division boundaries. DEFRA also mandated the development of an improved wage index. The act requires that hospitals be grouped by urban or rural location and census region when calculating the standardized payment rates. Separate average standardized amounts must be computed for hospitals located in rural areas as distinguished from urban areas.

RURAL REFERRAL CENTERS

Public Law 98-21 required the Secretary to provide adjustments and exceptions to take into account the special needs of regional and national referral centers (including those of 500 or more beds located in rural areas).

The final regulations published on January 3, 1984, provide that a hospital can qualify as a referral center if it meets either of the following criteria:

- It is located in a rural area and has 500 or more beds available for use; or

- At least 50 percent of its Medicare inpatient population is referred from other hospitals or from physicians not on the staff of the hospital. In addition, at least 60 percent of its Medicare patients must live more than 25 miles from the hospital, and at least 60 percent of all services it provides to Medicare beneficiaries are provided to beneficiaries who live more than 25 miles from the hospital.

Under the January 1984 regulations, hospitals that qualified under the first criterion were to be paid the applicable urban payment rate adjusted by the hospital's area wage index. No adjustment was provided for hospitals qualifying under the second criterion.

In final regulations published August 31, 1984, as a result of the passage of DEFRA and comments on a Notice of Proposed Rulemaking, a third criterion was added. Effective with cost reporting periods beginning on or after October 1, 1984, a rural hospital with fewer than 500 beds can also qualify as a referral center if it meets specific standards related to its case mix, number of discharges, percent of staff specialists, proximity of inpatient population, and percentage of referrals from other hospitals and physicians not on its staff. The regulations also provide that all rural hospitals qualifying as referral centers will be paid on the basis of the urban standardized amount adjusted by the hospital's area wage index.

As of September 30, 1984, five hospitals had qualified for the adjustment under the first criterion and one had qualified under the second criterion. Because the third criterion was not effective until October 1, 1984, no facilities had yet qualified under it.

HOSPITALS IN AREAS REDESIGNATED AS RURAL

Regulations provide a special adjustment of the rural average standardized amounts for hospitals located in areas redesignated as rural after April 20, 1983. Payment rates for hospitals that meet this criterion will be reduced to the appropriate rural rate over a 2-year period.

CENSUS DIVISION BOUNDARIES

The August 31, 1984, regulations also clarify the census division to which a hospital belongs when the metropolitan statistical area (MSA) or New England County Metropolitan Area (NECMA) in which the hospital is located crosses a census division boundary. Hospitals in the entire MSA or NECMA are deemed to belong to the census division in which most of the hospitals in that MSA or NECMA are located. If an equal number of hospitals are located in each part of an MSA or NECMA that crosses one or more census divisions, all the hospitals are deemed to belong to the census division with the highest Federal rate.

DEVELOPMENT OF NEW WAGE INDEX

In accordance with the requirements of DEFRA, the Department of Health and Human Services is undertaking a study to develop an improved wage index that explicitly addresses the part-time employment issue. Many rural hospitals, particularly in the Midwest, have expressed concern about the inability of the index used in standardizing and adjusting PPS rates to distinguish variations in the proportion of part-time personnel employed by hospitals. They

argue that because some hospitals employ a higher proportion of part-time personnel, relative wage levels in their locale are understated.

PPS ADJUSTMENTS, EXCEPTIONS, AND EXCLUSIONS

The law instituting the prospective payment system excludes several kinds of hospitals and hospital units from PPS, including psychiatric, long-term care, children's, and rehabilitation hospitals, and psychiatric and rehabilitation units operating as distinct parts of acute care hospitals. Under regulations specifying the conditions for exclusion, 439 psychiatric hospitals, 49 rehabilitation hospitals, 83 long-term hospitals, and 47 children's hospitals had been excluded from PPS as of the end of FY 84. In addition, 722 psychiatric units and 308 rehabilitation units had been identified for exclusion.

In response to allegations that the DRGs did not appropriately recognize alcohol and drug treatment, regulations authorized an additional temporary exclusion for both alcohol/drug specialty hospitals and alcohol/drug distinct-part units of acute care hospitals. This exclusion was granted to allow time for the DRGs to be reclassified and recalibrated to differentiate more appropriately between detoxification and rehabilitation treatment methods. Twenty-five hospitals and 216 units have been temporarily excluded.

The law also excludes from PPS hospitals located outside the 50 States and the District of Columbia but directs the Department to conduct a study to determine a method to include such hospitals. The study is under way.

Facilities and units excluded from PPS are paid reasonable costs subject to the rate-of-increase ceiling provided by Section 1886(b) of the law. Under that ceiling, Medicare reimbursement for hospital inpatient operating costs per discharge is limited to a target percentage increase over the preceding period's costs. Peer group limits that had previously applied in determining hospital reasonable costs are no longer in effect.

Hospitals in States which operate approved statewide reimbursement control systems are permitted to continue to be paid under those systems rather than PPS. Some 552 hospitals in Massachusetts, Maryland, New Jersey, and New York are paid under this authority. In addition, Veterans Administration hospitals and nonparticipating hospitals furnishing emergency services, regardless of location, are excluded from PPS. Health maintenance organizations may either retain per capita payments for inpatient hospital services furnished to enrollees or have Medicare pay the hospital directly under PPS.

SPECIAL PAYMENT ARRANGEMENTS FOR SOLE COMMUNITY HOSPITALS

A sole community hospital is a hospital that, because of such factors as isolated location, weather or travel conditions, or absence of other hospitals, is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries in a geographic area. The law requires that these hospitals be paid according to the formula in effect for the first year of the PPS, i.e., 75 percent hospital-specific rate and 25 percent Federal rate.

In addition, the law provides that, for cost reporting periods beginning on or after October 1, 1983, and before October 1, 1985, if an SCH experiences more than a 5 percent decrease in its total number of discharges compared to the immediately preceding cost reporting period, an additional payment adjustment will be made. The adjustment must fully compensate the hospital for the fixed costs it incurs during the period in providing inpatient services including the reasonable cost of maintaining necessary core staff and services.

Regulations published January 3, 1984, provide that a hospital already approved as an SCH or whose application was received by the fiscal intermediary before October 1, 1983, and subsequently approved will continue to qualify unless the area in which it is located has been redesignated as an urban area. The regulations then specify the criteria a hospital filing a new application must meet to qualify as an SCH.

As of September 30, 1984, 304 hospitals had qualified as SCHs.

SPECIAL PAYMENT ARRANGEMENTS FOR CANCER HOSPITALS

The law requires the Secretary to provide exceptions and adjustments for hospitals involved extensively in cancer treatment and research. Final regulations outlining the criteria for qualifying for this adjustment were published on January 3, 1984. They require that a hospital:

- Be recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute as of April 20, 1983;
- Demonstrate that it is organized primarily for cancer treatment and research; and
- Have at least 50 percent of its total discharges with a principal diagnosis of neoplastic disease.

A hospital meeting these criteria may elect during its first cost reporting period subject to PPS to remain under cost-based reimbursement, subject to the rate-of-increase limit.

As of September 30, 1984, four hospitals had qualified for this exception.

PROVIDER PAYMENT APPEALS

The January 1984 regulations amend the procedures hospitals follow in obtaining a hearing by the Provider Reimbursement Review Board (PRRB) on payment for inpatient hospital services under PPS. The revised procedures permit review in all cases except for items necessary to maintain budget neutrality and to avoid adversely affecting establishment of DRGs, the methodology for the classification of discharges within DRGs, and the appropriate weighting of each DRG.

In August 1984, HCFA published regulations authorizing additional administrative actions as a basis for prospective recalculation of a hospital's base-year costs under PPS. Such a recalculation may be made on the basis of a reopening of a cost report, a revision of a cost report determination, or a prehearing order or finding, in addition to a final administrative or judicial review decision.

PROSPECTIVE PAYMENT BENEFICIARY CHARGES

Interim regulations to implement PPS provisions precluded hospitals from charging beneficiaries for medically unnecessary care furnished before the stay passed the outlier threshold. Many hospitals requested that these regulations be revised to permit a hospital or its utilization review committee to notify beneficiaries when continuation of a hospital stay has been determined not to be medically necessary and to permit billing beneficiaries for continued care thereafter, even though the outlier threshold has not been passed. They indicated that hospitals must be able to exercise this authority as early as possible in order to control costs under PPS.

Regulations published on January 3, 1984, reflect these requested changes but contain certain safeguards. For example, the attending physician or the hospitals's medical review entity must agree with the hospital's determination, and the hospital must provide the beneficiary (or the beneficiary's representative) 3 days' notice (2 days between the notice and the effective date of noncoverage).

PROVIDER APPEALS OF DRG ASSIGNMENTS

HCFA developed an appeals mechanism under PPS which enables a hospital to challenge an intermediary's initial DRG assignment or a medical review entity's revised DRG assignment.

OTHER RULE CHANGES

The August 1984 regulations also modify other PPS provisions, including day-outlier payments for transfer cases and, under certain circumstances, additional payments to a hospital for inpatient renal dialysis.

OTHER INITIATIVES

COST LIMITS FOR SKILLED NURSING FACILITIES

Section 2319 of DEFRA requires, for cost reporting periods beginning on or after October 1, 1982, but before July 1, 1984, that cost limits for routine services provided by hospital-based and freestanding skilled nursing facilities (SNFs) must be similar to those in effect before the passage of TEFRA. That means that the limits for freestanding facilities must continue to be set at 112 percent of the average per diem operating costs, and the limit for hospital-based facilities must be set at 112 percent of the average per diem operating cost of freestanding facilities. Each category will be further divided into urban and rural groupings.

Section 2319 also requires that the routine cost limit for urban or rural hospital-based SNFs for cost reporting periods beginning on or after July 1, 1984, must be set at the appropriate freestanding facility limit plus 50 percent of the difference between the freestanding facility limit and 112 percent of mean operating costs for hospital-based facilities. Cost differences between hospital-based and freestanding SNFs attributable to excess overhead allocation resulting from Medicare reimbursement principles are to be recognized as an add-on to the cost limit for hospital-based SNFs.

COST LIMITS FOR HOME HEALTH AGENCIES

Limits on home health agency (HHA) costs were first established effective July 1, 1979, based on a classification system that only distinguished between urban and rural providers. The limits, which were derived from agency per visit costs for each of six Medicare-covered services, were set at the 80th percentile of per visit costs. However, the limits were applied on an aggregate basis because cost-finding methods used by providers made it impractical to apply the limits directly to the per visit cost of individual services. Adjustments were permitted for inflation.

Mandatory uniform cost-finding for HHAs, effective October 1, 1980, will eventually permit the direct application of limits for each type of service.

Effective July 1, 1980, HCFA revised the HHA cost limits by adopting several features common to the hospital and SNF methodologies, using an urban/rural classification system with separate categories for hospital-based and freestanding agencies and incorporating the hospital wage index. The Omnibus Budget Reconciliation Act of 1981 established the level of payment at the 75th percentile.

The enactment of TEFRA required that hospital-based agency limits be based on the costs of freestanding agencies. To establish the limits for hospital-based agencies, regulations were published in September 1982 which added 13 percent of median hospital-based agency costs to the freestanding limit to recognize additional overhead costs allocated to the HHA as the result of the Medicare cost-finding methodology.

Limits were again revised, effective July 1, 1984, continuing the methodology in the previous schedule and incorporating changes in inflation estimates and MSA designations. The new schedule expands the adjustment for prevailing wage levels to all labor-related costs and excludes high and low costs in establishing the limits.

COSTS INCURRED FOR UNION ACTIVITIES

Under Section 107 of TEFRA, instructions were issued in April 1984 providing that any costs incurred on or after September 3, 1982, that are directly related to influencing, coercing, or otherwise interfering with or restraining employees in the exercise of their rights regarding unionization are not allowable for Medicare reimbursement purposes. Provider costs incurred in activities which are consistent with the National Labor Relations Act, however, continue to be allowable costs of operation provided they are not directly related to influencing employees with respect to unionization and are not unreasonable.

COST REPORT QUESTIONNAIRE

The Provider Cost Report Questionnaire, Form HCFA-339, issued in February 1984, was developed to assist providers in preparing acceptable cost reports. It answers pertinent questions about key reimbursement concepts in the cost reports and provides information needed to support certain financial and statistical entries on the report. Its use was effective for cost reports filed after February 28, 1984.

SWING-BED HOSPITAL INSTRUCTIONS

In January 1984, instructions on reimbursement for swing-bed hospitals were issued. The instructions explain and illustrate reimbursement of both inpatient hospital services and long-term care services furnished by swing-bed hospitals. The instructions also address the integration of swing-bed reimbursement methodology into the prospective payment system.

PARTICIPATING PHYSICIANS AND THE FEE FREEZE

Section 2306 of DEFRA established a 15-month freeze on Medicare reimbursement for physician services (effective July 1, 1984, through September 30, 1985) and created a physician participation program. A participating physician (or group of physicians) who agrees to accept assignment for all services provided to Medicare patients and agrees to accept the Medicare-allowed amount as payment in full, less 20 percent coinsurance and deductible, may increase his/her billed charges, effective as of the next reasonable charge update. Nonparticipating physicians, however, may not increase charges to Medicare beneficiaries during the freeze period and are subject to civil money penalties if they knowingly and willfully do so.

In addition to exemption from the limitation on fee increases during the freeze period, physicians are offered these incentives to participate: inclusion in identification to beneficiaries on carrier-operated, toll-free telephone lines, certificates or other emblems for display, and direct lines for electronic submission of claims.

HCFA developed physician participation agreement forms, explanatory fact sheets, and covering letters for carriers to release to physicians in late August 1984. HCFA also issued guidelines to carriers for processing the agreements and handling claims from participating physicians.

PAYMENT FOR CLINICAL DIAGNOSTIC LAB TESTS

Guidelines implementing Section 2303 of DEFRA require establishment and use of fee schedules on a carrierwide basis (not to exceed a statewide basis) for payment of clinical diagnostic laboratory tests performed in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients, for services rendered on or after July 1, 1984. The fee schedule amounts are set at 60 percent of the prevailing charges for laboratory tests performed in physicians' offices and by independent laboratories. For outpatient laboratory tests, the fee schedule amount is 62 percent of the prevailing charges.

COVERAGE OF HEMOPHILIA CLOTTING FACTORS

Before enactment of DEFRA, drugs and biologicals that could be self-administered were not covered under Part B. Section 2324 of DEFRA, however, allows Part B reimbursement for blood clotting factors, and items related to their use, for hemophilia patients competent to use them to control bleeding without medical or other supervision. Instructions were issued to provide guidelines for implementing these provisions.

SPECIAL ENROLLMENT PERIOD FOR THE WORKING AGED

Section 2338 of DEFRA provides special enrollment and premium considerations for individuals aged 65 through 69 who do not enroll promptly or who terminate enrollment in Part B because of coverage under the working-aged provision of the Social Security Act (Section 1982(b)(3)(A)). This permits exclusion from calculation of the premium penalty for late enrollment of those months of coverage under both Part A and an employer group health plan that is primary payer of health care benefits. DEFRA allows a special 7-month enrollment period in Part B when the employer group health plan is no longer primary payer. Manual instructions were distributed to all SSA field offices and operating components in September 1984 to implement these changes.

READABILITY STANDARDS FOR PART B REVIEW DETERMINATION LETTERS

Instructions were issued in August 1984 to reflect the agreement by HCFA in David v. Heckler (E.D. N.Y.) to write review determination letters at a 6th-to-7th-grade reading level. In addition, the letters must give beneficiaries sufficient information about the basis for denial that they can pursue their appeal rights effectively.

REPRESENTATION OF BENEFICIARIES IN PART A APPEALS

Instructions were issued in January 1984 to preclude a Part A provider or its employees from representing a beneficiary in the Part A appeals process. This policy is intended to protect the beneficiary from potential conflicts of interest.

COVERAGE OF HEART TRANSPLANTATION

In 1984, HCFA began a broad study of all aspects of Medicare coverage of heart transplantation, including social, economic, and scientific issues. Study results will be used to develop national coverage policy on heart transplantation, a procedure that Medicare does not now cover because it is still regarded as experimental.

CONFIDENTIALITY AND DISCLOSURE

A policy change has been made to allow disclosure of identifiable information without beneficiary consent to an individual or organization for epidemiological and other research and statistical purposes, provided certain criteria and safeguards are met.

PROVIDER REIMBURSEMENT APPEALS

Changes made by Section 955 of Public Law 96-499 now make it possible for a provider that requests and has the right to obtain a hearing by the Provider Reimbursement Review Board to bypass the hearing and obtain judicial review of any action of the intermediary that involves a question of law or regulation relevant to the matters in controversy, whenever the PRRB determines that it is without authority to decide the question. The PRRB may determine that it lacks the authority either on its own motion or at the provider's request.

CHAPTER IV. HIGHLIGHTS OF THE DEFICIT REDUCTION ACT OF 1984

INTRODUCTION

Public Law 98-369, the Deficit Reduction Act of 1984 (DEFRA), enacted July 18, 1984, added a number of new provisions that affect beneficiaries and providers of services, as well as fiscal intermediaries involved in the operation of the Medicare program. This chapter briefly discusses the law's highlights.

MEDICARE REIMBURSEMENT AND BENEFIT CHANGES

DEFRA modifies the working-aged provision to make Medicare the secondary payer to employer-provided group health insurance in cases in which a spouse is between the ages of 65 and 70 and the worker is under age 65.

For calendar years 1986 and 1987, DEFRA sets the monthly Part B premium paid by enrollees at an amount equal to 25 percent of the Supplementary Medical Insurance program costs for aged beneficiaries.

The act also provides for the establishment of fee schedules for physicians' laboratory and independent clinical laboratory services on a statewide, regional, or carrier-wide basis for the fee-screen year beginning July 1, 1984, and mandates assignment for independent laboratories and hospital-based laboratories furnishing services to outpatients.

Physicians' fees are also affected by DEFRA. For 15 months, beginning July 1, 1984, the act freezes Medicare customary and prevailing charges for physician services at the levels that were in effect for the 12-month period ending June 30, 1984; updates physicians' customary and prevailing charges on October 1 rather than July 1 of each year; and permits physicians to sign voluntarily 1-year participation agreements before October 1 of each year.

In addition, the act places a floor on customary charges for teaching physicians at 85 percent of the Medicare prevailing charges and grants the Secretary discretion in defining teaching physicians.

DEFRA provides that charges will be considered nominal if they are less than or equal to 60 percent of costs. The Department of Health and Human Services (HHS) is required to segregate inpatient and outpatient services when determining the lesser of cost or charges, and nominal charges.

For fiscal years 1985 and 1986, DEFRA limits the rate of increase for both prospective payment system (PPS) hospitals and PPS-exempt hospitals and units at the market basket plus one quarter of one percentage point, subject to budget neutrality.

In other provisions affecting prospective payment, DEFRA grants hospitals located in counties redesignated as rural a 2-year transition to rural rates; deems hospitals located in a metropolitan statistical area (MSA) to be in the region in which the greatest number of hospitals are located or the region which accounts for the greatest number of Medicare discharges; permits a hospital classified as a rural hospital to appeal to be classified as a rural referral center; and requires HHS to review and report to Congress on various methods to refine PPS under Medicare.

DEFRA also establishes separate payment limits for free-standing and hospital-based skilled nursing facilities (SNFs) and requires HHS to report to Congress on a prospective payment system for SNFs.

With respect to the prospective payment wage index, the act requires HHS, in consultation with the Secretary of Labor, to conduct a study and develop an appropriate hospital area wage index that accounts for the wage differences of full-time and part-time workers, and requires hospital payment amounts to be adjusted to reflect any changes by increasing or decreasing payments in succeeding cost reporting periods.

In other provisions DEFRA:

- Mandates the reimbursement of certified registered nurse-anesthetists on a passthrough basis through September 30, 1986.

- For hospitals and SNFs, restricts the reevaluation of an asset that undergoes change of ownership to the lesser of the allowable acquisition cost under Medicare to the owner of record or the purchase price.

- Requires beneficiaries to pay the 20 percent Medicare Part B coinsurance on durable medical equipment provided by home health agencies.

- Requires HHS to deny coverage under the Medicare program for debridement of mycotic toenails if performed more frequently than once every 60 days.

- Authorizes through October 1, 1986, coverage for hospice services for the terminally ill with a life expectancy of 6 months or less. Hospices are required to provide routinely all "core services" (nursing care, medical social services, physician's services, and counseling services directory) and may only contract these services to supplement employees under extraordinary circumstances.

OTHER CHANGES

DEFRA permits competitive bidding to replace contractors whose performance has repeatedly ranked in the lowest 20th percentile; requires standards for Part A and Part B contracts to be published in the Federal Register; and requires the number of home health agency regional intermediaries to be reduced from 47 to 10 by July 1, 1987.

With respect to the working aged, DEFRA waives the Part B enrollment penalty for workers and their spouses aged 65 through 69 who elect private coverage; establishes special enrollment periods for such workers; and clarifies that the waiver may apply only for the period during which an individual continues to be covered under an employer's group health benefits plan.

The act also:

- In cases where Medicare is a secondary payer, establishes the right of Medicare to recover payment directly from third parties even if the beneficiary does not bring action.

- Provides that HHS may rely on accrediting organizations to determine whether rural health clinics, laboratories, clinics, rehabilitation agencies, psychiatric hospitals, and public health agencies meet Medicare requirements.

- Requires PPS-exempt hospitals to contract with peer review organizations to perform quality reviews.

- Directs HHS to develop and publish a definition of a hospital that serves a disproportionate number of low-income individuals or patients entitled to Part A of Medicare.

DEFRA also provides that the Administrator of the Health Care Financing Administration (HCFA) be appointed by the President with the advice and consent of the Senate.

CHAPTER V. REPORT ON RESEARCH, DEMONSTRATIONS, AND EVALUATIONS

INTRODUCTION

The most recent data show that total health care expenditures in the United States rose at an average annual rate of 11.9 percent from 1970 to 1983 (Health Care Financing Review, winter 1984). In this context of significant change, research and demonstration activities yield valuable information for decisionmaking.

During FY 84, the Office of Research and Demonstrations (ORD) of the Health Care Financing Administration (HCFA) conducted intramural and extramural projects that studied, demonstrated, and evaluated reimbursement, coverage, eligibility, and management alternatives to the present structure of the Medicare program. ORD also measured and evaluated the impact of HCFA's programs on (1) beneficiary use of program benefits and access to services, and (2) provider charges and program reimbursements for the use of these benefits.

Research and experimentation in support of the Medicare program was authorized in the Social Security Act and the Social Security Amendments of 1967 and 1972, as well as in the National Health Planning and Resources Development Act of 1974. HCFA's research and development (R&D) program develops and tests innovative ways to promote efficiency and quality in Medicare and other HCFA programs. It assesses the impact of HCFA programs on health care costs, program expenditures, beneficiary access to services, health care providers, and the health care industry. Reports are prepared that describe and analyze the use and costs of program benefits. Studies are undertaken to explore in greater detail the structure and dynamics of the various sectors of the health care industry.

During FY 84, in addition to its intramural projects, HCFA spent almost $33 million for grants and contracts to conduct research, demonstration, and evaluation projects. These were organized into seven program areas: hospital payment, physician payment, long-term care, alternative payment systems, program analysis and evaluation, coverage, and prevention.

Information on HCFA R&D projects can be obtained from the publications office identified at the end of this chapter. The status report that describes each project may be of particular interest. In FY 1984, two editions were issued:

- Health Care Financing Status Report: Research and Demonstrations in Health Care Financing, April 1984 edition, USGPO 1984, 421 100 15201. Available from the National Technical Information Service, accession number PB 84-229335.

- Health Care Financing Status Report: Research and Demonstrations in Health Care Financing, October 1984 edition, USGPO 1984, 421 100 15224. Available from the National Technical Information Service, accession number PB 85-124170.

HOSPITAL PAYMENT

Research on hospital classification and case mix provided a basis for Medicare reimbursement reform, beginning with refinements to routine per diem cost limits, leading to expanded total case limits, and resulting in the prospective payment system (PPS) for hospitals, based on diagnosis-related groups (DRGs). Prior to passage of the PPS legislation (the Social Security Amendments of 1983), HCFA studies resulted in a number of major modifications in hospital cost-reimbursement policy, producing significant program savings. Examples of these changes include elimination of the private-room differential under Medicare, elimination of the 8.5 percent Medicare routine nursing differential, and reductions in Medicare and Medicaid payments to hospitals for malpractice insurance. These three reforms were estimated to save $800 million in program costs based on actuarial projections for FY 84. These savings were incorporated into the PPS cost base.

The studies mandated by the Social Security Amendments of 1983 and the Deficit Reduction Act of 1984 (DEFRA) seek to resolve many reimbursement issues and to provide policymakers with current information on the progress of the system. As required by this legislation, HCFA worked on the First Annual Report to Congress on the Impact of Medicare PPS. The report documents important changes in Medicare program statistical trends that occurred during the first year of PPS.

HCFA statisticians and analysts also helped design a method to detect providers who may be increasing admissions unnecessarily in order to take advantage of the new reimbursement rules under PPS and a study of the causes of the increase in the Medicare case mix between 1981 and 1984. Also in FY 84, HCFA continued to participate in hospital prospective payment demonstrations through waivers of standard Medicare/Medicaid reimbursement principles.

Intramural work produced reports on:

- Public general hospital costs.
- Studies of hospital departmental costs (labor-room day cost allocations).
- Costs of disproportionate-share hospitals (low-income and Medicare).

- o Analyses of skilled nursing facility DRGs.
- o Analyses of the indirect teaching adjustment formula.
- o Alternatives for performance recalibration of DRG weights.

A compendium of articles on alternatives for refining case-mix measurement was assembled and published in the Health Care Financing Review, 1984 Annual Supplement.

Work will begin on reports due to Congress in spring 1985 concerning sole community hospital occupancy variations; treatment of uncompensated-care costs; adjustments that might be appropriate for large rural teaching hospitals; and the feasibility of hospitals' providing cost-of-care information to patients. Projects were initiated to support other major PPS issues raised by Congress, including assessments of:

- o Rural versus urban hospital cost and payment differences.
- o The feasibility of extending PPS to children's hospitals, long-term care hospitals, and psychiatric and rehabilitation units and hospitals.
- o DRG refinements for severity of illness or intensity of care.
- o Adequacy of outlier payments.
- o Impact of admissions and the need for admission controls on volume adjustments.
- o Cost-shifting and the feasibility of extending PPS to all payer systems.

A series of projects was initiated for developing improved methods for assessing the quality of care provided to Medicare beneficiaries. Finally, HCFA supported research in outpatient care classification and reimbursement strategies.

PHYSICIAN PAYMENT

Recent HCFA studies documented that the current method of Medicare reimbursement results in excessive payments to certain physicians. This evidence supported provisions in the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) to change reimbursement policy for provider-based physicians, inpatient radiologists and pathologists, as well as physicians providing services in outpatient departments and assistants in surgery.

HCFA worked on physician reimbursement methods that will provide alternatives that do not increase inflation as does the current fee-for-service system. A new Part B data base was assembled that will be used to examine a number of alternatives. In response to Section 603 of Public Law 98-21, the Social Security Amendments of 1983, research began addressing the advisability and feasibility of pursuing the implementation of prospective payment for inpatient hospital services of physicians. Work also continued on developing and refining relative value scales and fee schedule alternatives and carrierwide capitation approaches.

HCFA began preparing to study the effects of the provisions of TEFRA which froze physicians' fees and instituted the Medicare participating physicians program. The results of this study will be used to update and refine the Medicare Economic Index, which is estimated to have resulted in a 3.5 percent savings in Medicare reimbursements. Other related work included comparative studies of services commonly provided in either physicians' offices or outpatient departments and analyses of hospital-based ambulatory care services.

LONG-TERM CARE

HCFA's long-term care research activities involve the use and analysis of existing data, either collected by survey or abstracted from other data sources. In FY 84, long-term care research focused primarily on describing and explaining the demand for long-term care and the basic economic underpinnings of the long-term care industry. In addition, considerable effort was given to the development of a methodology to measure the quality of long-term care provided in different settings.

HCFA's long-term care demonstrations require the development of a rigorous research design. Within the design, a specific intervention is introduced into a live situation and the outcomes are observed. The evaluation findings, based on the outcomes observed in the demonstrations, form the basis for future policy recommendations regarding the Medicare program.

RESEARCH

Long-term care research can be classified according to four objectives: developing prospective payment systems for long-term care; promoting alternatives to long-term care; assessing and evaluating long-term care programs; and supporting data development and analysis.

Prospective Payment

The current payment system has been criticized for failing to differentiate according to the resources consumed by each nursing home resident. Solving this problem requires appropriate systems to quantify the long-term care needs of

the elderly patient. A variety of methods were designed, including case mix, to evaluate resource consumption of nursing home patients with the goal of developing more appropriate payment systems. Several States are using different methods of nursing home payment, some of which incorporate case mix. Studies are being developed to evaluate the design and implementation of these systems and their effectiveness in achieving the goals of containing costs, maintaining or improving quality, and ensuring access.

Alternatives to Long-Term Care

Research activities that consider alternatives to existing patterns can be classified into two major divisions: community-based alternatives to institutional care, and alternatives to current financing mechanisms for long-term care.

Community-based, noninstitutional approaches are being developed with the objectives of avoiding or delaying unnecessary institutionalization, maximizing the independence and well-being of the elderly, and providing care in the most cost-effective manner. The studies focus on such issues as family care-giving, utilization of home health services, determinants of public and private contributions in long-term care provision, and provision of noninstitutional services by nursing homes.

Alternatives to current financing mechanisms are being investigated. Two studies will begin to examine the potential for increased family support, either through tax incentives or cost sharing under family-responsibility laws. The market for long-term care insurance was also assessed. Another area of examination is the use of life-care centers as a private financing mechanism for long-term care.

Program Assessment

Another group of research studies investigated specific aspects of Medicare long-term care policies.

As required by legislation, work continued on three studies concerning coverage and reimbursement of home health services. Two studies, mandated by Public Law 96-499, the Omnibus Reconciliation Act of 1980, assessed Medicare home health coverage for respiratory therapy and registered dietitian services. The third study, mandated by Public Law 97-414, the Orphan Drug Act, analyzed current and alternative payment methods for home health services.

In October 1982, Congress expanded the Medicare benefit structure to include hospice care and created a new type of provider--hospices. The hospice benefit is authorized until October 1986. HCFA is evaluating the program experiences of this benefit.

In recent years, State and Federal governments have initiated a number of programs to improve the delivery and financing of long-term care services. Another project assessed a preadmission screening program for nursing home placement. Data from this study suggest that screening and minimal-care management can be effective in identifying those elderly who can be appropriately cared for in a community-based setting at lower cost.

Finally, HCFA investigated the expanded role of nurses in long-term care. A study evaluated the potential of the use of geriatric nurse-practitioners for improving outcomes of care and containing costs in skilled nursing facilities.

Data Development and Analysis

In the past, information on the health status and health care utilization of the long-term care population has been drawn almost exclusively from cross-section surveys such as the National Nursing Home Survey. Although useful, cross-section data have limitations.

Two longitudinal surveys were conducted to provide a better picture of the transitions of disabled elderly living in households and of institutionalized patients. The Long-Term Care Survey interviewed 6,000 disabled elderly living in households in 1982. In 1984, these same persons were resurveyed to determine how they have fared since 1982. Those persons who are in institutions as well as persons who were not previously disabled were included. The Admission Cohort Survey, a part of the proposed National Nursing Home Survey, will track persons for a minimum of 12 months after admission to nursing homes.

Longitudinal analyses and projections were also being conducted with state-of-the-art statistical methods for using mortality data to estimate and project the incidence of specific chronic diseases (e.g., cancer).

Another project was funded in July 1984 to collect the fourth series of self-reported information from the Massachusetts Health Care Panel Study cohort. The cohort consists of persons who, in 1974, were selected in a statewide probability sample of persons 65 years of age or over during the last decade.

Certain information concerning long-term care services is routinely abstracted from the Medicare claims payment system and reported by HCFA. These are long-stay hospitals, skilled nursing facilities, and home health services.

HCFA sponsored a conference for policymakers and others in Washington, D.C., January 24, 1984, to discuss several initiatives in the financing and provision of long-term care. A report of the proceedings of the conference was published. The report, "Long-Term Care Financing and Delivery Systems: Exploring Some Alternatives," is available only from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (stock number 017-060-00158-5).

DEMONSTRATIONS

HCFA conducts demonstrations in long-term care for the growing numbers of elderly, disabled, and chronically ill. In FY 84, this program area encompassed studies of the populations in need of care, factors affecting choice of different kinds of care, effects of changes in public funding of services outside institutions, economics of the long-term care industry, and methods to reimburse nursing homes prospectively. HCFA also funded demonstrations of community systems that help elderly clients obtain services and monitor the appropriateness of services.

The 10 sites participating in the HHS National Channeling Demonstration continued to screen, assess, and serve clients determined to be at risk of institutional care. This demonstration was designed to investigate two channeling models: a single-entry, community-based system of case management and assessment using existing health and social services (basic model), and a single-entry, community-based system of case management and assessment with an array of services to be reimbursed by the Medicare/Medicaid programs (complex model).

The Aid to Families with Dependent Children (AFDC) Home Health Aide Demonstration was developed to study whether AFDC recipients can be trained and employed to provide home care services to elderly or disabled individuals who otherwise would require institutional care. Section 966 of the Omnibus Reconciliation Act of 1980 (Public Law 96-499) authorized the Secretary of Health and Human Services to "... enter into agreements with States ... for the purpose of conducting demonstration projects for the training and employment of eligible participants as homemakers or home health aides..."

In an effort to develop alternative payment methods for HHAs, HCFA began a research strategy to test purchasing and payment methods that bring competitive market forces into the home health care field. HCFA began developing several models of competitive bidding for home health services under Medicare and Medicaid.

A 3-year project continued that examines the effects of providing training and respite care to families that maintain frail elderly family members at home. Under this demonstration, 600 patients (500 experimental and 100 control) are being studied to test the effectiveness of these services on the ability and willingness of families to retain primary responsibility for the care of aged members.

In addition, a project to develop, test, and refine a long-term care prospective reimbursement system based upon clusters of patient characteristics continued. The system will build upon the results of research which developed clusters of patients in relation to staff resources used (resource utilization groups). The purpose of the project is to promote efficiency by associating payment levels with patient characteristics that indicate the amount of services patients actually need.

In another project, four demonstration sites were approved for participation in the social health maintenance organization (HMO) project, as mandated by the Deficit Reduction Act of 1984. These sites began implementing a concept which integrates health and health-related services under the direct financial management of the provider of services. All services will be provided by or through the social HMO at a fixed, prepaid capitated sum.

ALTERNATIVE PAYMENT SYSTEMS

Since 1980, HCFA has supported several HMO demonstrations that have tested alternative reimbursement methods. The HMOs enrolled more than 240,000 Medicare beneficiaries in benefit plans that are richer than fee-for-service Medicare, and at a cost of 5 percent less than fee-for-service Medicare. The demonstration led to passage and implementation of Section 114 of Public Law 97-248, TEFRA. These demonstrations test various innovative concepts:

- A health-broker model in which Medicare beneficiaries receive a non-negotiable voucher to purchase health care offered by several HMOs and competitive medical plans (CMPs). Beneficiaries were counseled on various aspects of the selection process.

- o A new reimbursement method using the beneficiaries' prior use of Medicare services (hospitalization and Part B service) as an additional factor in the adjusted average per capita cost (AAPCC) methodology.

- o A reduced-reimbursement method in which three HMOs located in competitive areas receive reimbursement at 85 percent of the AAPCC, rather than the TEFRA-mandated 95 percent.

PROGRAM ANALYSIS AND EVALUATION

HCFA maintains an active agenda of analyses to assess the impact of programs on beneficiaries and to determine the extent to which the programs meet Agency goals.

PROGRAM ANALYSIS

In program analysis activities, data are collected and studied to analyze patterns and trends in the use of covered services and to measure the financial burden on the beneficiaries for medical care. Studies are designed to address these basic issues and to assess other issues important to the health of the beneficiaries, including access to needed care and the timely delivery of cost-effective and efficacious services.

One of the analyses undertaken in FY 84 was a study of aged persons dually entitled to Medicare and Medicaid. This subgroup of Medicare beneficiaries, called "crossovers," is of special interest because of the enrollees' higher rates of poverty and poorer health.

Another major area of study involved Medicare beneficiaries' enrollment in HMOs. HCFA's payment mechanism, known as the AAPCC, adjusts the payment to HMOs for Medicare enrollees for five factors known to influence the level of Medicare outlays: age, sex, institutional status, welfare status, and county of residence. An important issue is the adequacy of the AAPCC mechanism, especially in cases of biased selection.

HCFA also turned its attention to a somewhat neglected group of beneficiaries, the disabled. More research has been devoted to the Medicare aged population than to disabled enrollees, yet disabled enrollees comprise about 10 percent of Medicare enrollment and Medicare expenditures for them have been rising faster than for aged enrollees. A major study was under way to analyze patterns of health services used by the disabled under Medicare. In particular, this population was being analyzed by type of disability award, i.e., disabled worker, adult disabled in childhood, or disabled spouse.

An evaluation of Part B fixed-price contracts for Medicare carriers continued during 1984. This project was designed to evaluate the Medicare Part B fixed-price carrier experiments in three geographic areas. The purpose of the study was to determine whether the fixed-price method reduced Federal program costs through more efficient processing, while maintaining quality of carrier performance.

In FY 84, HCFA began to investigate a fundamental, unanswered question in medical care: Why are there such large, unexplained differences among geographic areas in the incidence of many procedures? The study examined whether high use rates of certain procedures in selected geographic areas reflect inappropriate overuse and, to a lesser extent, whether low procedure rates in other areas reflect underuse.

Two studies on surgical hospitalization were conducted in FY 84. The first (using 1979 and 1980 data) examined post-surgical mortality among the aged after eight common operations. The second study, involving the same group of procedures, investigated the question of whether an association exists between mortality rates and annual volume of operations performed at individual hospitals. A third study was initiated on rehospitalization following these same surgical procedures. These studies will provide baseline data for evaluating the impact on beneficiaries of Medicare's prospective payment system to hospitals.

An article published in the Health Care Financing Review, spring 1984, described patterns of Medicare use by persons during their last 2 years of life.

Studies of the Medicare aged population have shown that expenditures are concentrated among a small percent of service users, particularly for Part A services. The question often arises as to whether Medicare expenditures have become more or less concentrated among a few heavy users of service over time. In FY 84, HCFA conducted a study that looked at the concentration of Medicare expenditures among the aged for 3 separate years (1969, 1975, and 1982), using reimbursement data for a 5 percent national sample of beneficiaries.

EVALUATION

In FY 84, HCFA was responsible for program evaluations assessing the effectiveness of specific national programs or policies. Major evaluations are mandated by Congress, initiated by the Secretary, or determined by administrative initiative. Administrative initiatives were in progress for estimation of inappropriate hospital utilization.

Four congressionally mandated program evaluation studies related to Medicare were under way in 1984. The first was an evaluation of the impact of the rural swing-bed program (Public Law 96-499). The evaluation included analyses of the program's impact on, access to, and use of long-term care services in rural areas with shortages of nursing home beds. This project assessed whether such services furnished in small (fewer than 50 beds) rural hospitals were cost effective and comparable in quality to the services furnished in certified nursing home facilities.

The second congressionally mandated study concerned "Medigap," or supplementary insurance. The purpose of the study was to ascertain the effectiveness of State insurance regulations in permitting more informed choice, reducing duplicative coverage, and limiting marketing abuses.

In the third study, a strategy was developed for the evaluation of the new Medicare hospice benefit enacted by TEFRA.

Finally, there is a broad-ranging research, demonstration, and evaluation program in the area of end-stage renal disease (ESRD). Information about these activities is included in the ESRD chapter of this report.

COVERAGE

Research, demonstration, and evaluation projects in FY 84 assessed the costs and benefits of expanding Medicare and Medicaid coverage to include new benefits or alternative methods for providing the benefits under study, and to address the effects of these alternatives on beneficiaries. Initiatives were under way in expanding ambulatory-service coverage to Medicare beneficiaries for alcoholism, mental health services, urban health clinic services, end-stage renal disease, and Medicare-funded heart transplants.

Both the alcoholism services and mental health services demonstrations were aimed at testing the cost effectiveness of providing Medicare and/or Medicaid coverage for services provided in ambulatory centers that currently do not have provider status.

The urban health clinics demonstration examined the relative advantages and disadvantages of reimbursement on the basis of costs and fee-for-service for physician-directed clinics employing physician assistants or nurse practitioners.

HCFA also began a project that is exploring different approaches for testing competitive financing in the ESRD program. The possibilities include competitive bidding; capitation covering all medical care costs, as well as other options with coverage limited to outpatient ESRD services; and voucher payments allowing patients to share in the financial saving of cost-reducing shifts.

A national heart transplantation study was designed to evaluate the scientific, economic, ethical, legal, and social factors related to heart transplantation. It includes the collection and analysis of data on organ procurement, need for transplantation, costs, and survival of transplant patients.

DATA BASE AND STATISTICAL ACTIVITIES

The central administration of the Medicare program at the Federal level has permitted the development of a uniform, multipurpose Medicare data base that serves the needs of planners, researchers, and policymakers. HCFA uses this claims-based statistical system, together with other reporting systems, to prepare a wide variety of statistical and analytical reports and studies on the utilization and reimbursement of health care services financed by Medicare and Medicaid.

HCFA maintains a statistical program for generating information on the ongoing operation of the Medicare and Medicaid programs. Program Statistics reports provide data on the number and characteristics of program beneficiaries; the number, distribution, and characteristics of providers certified to furnish services to Medicare beneficiaries; and the patterns of use of program benefits by beneficiaries. Use of benefits is examined by the characteristics of the person using them, the providers furnishing the services, and the distribution of charges and reimbursements to beneficiaries and providers. The purpose of these reports is to show trends and to examine the factors that may be influencing those trends.

Because of the limitations in existing statistical reports for the Medicaid program, HCFA began, in 1981, to develop a new source of Medicaid data at the Federal level. This pilot project, known as "Tape-to-Tape," has acquired detailed data on enrollment, use of services, expenditures, and providers from individual State Medicaid management information systems.

A HCFA report in preparation during 1984 on the availability of and access to Medicare providers and suppliers of services showed significant variations by geographic area.

Through linkage of Medicare eligibility and claims files, a continuous history of 5 percent of all Medicare beneficiaries links their use of Medicare benefits, beginning with benefits received in 1974. Work progressed on projects to link this continuous-history sample to other data bases outside HCFA to expand the range of analyses possible on Medicare beneficiaries.

In addition to reports based on the Medicare and Medicaid claims payment systems, HCFA planned a series of reports from the National Medical Care Utilization and Expenditure Survey (NMCUES) of 1980. NMCUES collected detailed socio-demographic, health status, health insurance, and health care payment data that were not available from either the Medicare or Medicaid administrative record systems. The data will allow analysis of policy issues relating to out-of-pocket costs, access to health care, and Medicaid use by social and ethnic groups.

Finally, HCFA maintains a data base on national health spending by sector of care and by source of payment. The Health Care Financing Review, winter 1984, reported trends in spending and sources of payment through the end of the previous calendar year. Projections of national health spending by sector and by source of payment through 1990 appeared in the Health Care Financing Review, spring 1984. The national health expenditure data base also includes distribution of health spending and sources of payment by age group, with special emphasis on persons 65 years of age or over.

PREVENTION

Few insurers provide coverage and reimbursement for preventive services. Usually insurers, including Medicare, restrict coverage to services that treat, rather than prevent illness. Although proponents of preventive services assert that health improvement and cost savings would result from an expanded preventive services package, the efficacy and economy of preventive services have not been tested on the Medicare beneficiary population. Three projects or sets of projects in this area were in progress in 1984.

In the first project, HCFA and the Robert Wood Johnson Foundation continued to support demonstrations to determine whether primary care clinics affiliated with municipal outpatient departments could improve access to care and contain costs in urban areas. Twenty clinics in five cities provided routine and ancillary services in this demonstration.

A second study focused on the effectiveness of preventive care on various categories of medical expenditures continued. The study uses data from the Health Insurance Study, a social experiment in which approximately 8,000 individuals were assigned to several different health insurance plans at six sites across the country.

Finally, an intervention project continued at an urban university hospital. The project attempts to prevent future utilization of health and long-term care services by training chronically ill Medicare beneficiaries and their

care partners in self-care techniques. The purpose is to reduce the high rate of rehospitalizations for certain chronic conditions (for example, heart disease) through good home-care monitoring.

HCFA'S R&D PUBLICATIONS PROGRAM

HCFA continued its research publications program through several series of publications that cover research and demonstration activities and statistical information on the Medicare program. These were part of a dissemination effort to reach interested user groups and to provide research results for policymakers and health professionals. The series include:

- Health Care Financing Program (Brown Series)--Indepth reports that provide information on Medicare and Medicaid program operation and use. The reports include data on enrollment, providers, reimbursement, and recipients.

- Health Care Financing Research Reports (Purple Series)--Reports on major intramural studies and projects conducted by HCFA. The reports contain significant findings that affect HCFA programs and serve as a basis for making program changes.

- Health Care Financing Grants and Contracts Reports (Blue Series)--Final reports of extramural projects funded by HCFA. Topics include hospital cost containment, long-term care reform, physician reimbursement, beneficiary access to and use of services, and health systems organizations.

- National Medical Care Utilization and Expenditure Survey Reports (Rust Series)--Reports on survey methodology and survey findings. Findings include information on use of medical care and health and demographic characteristics of persons and families.

- Health Care Financing Special Reports (Orange Series)--Single-theme reports that provide either indepth coverage of an important issue in health care financing or a collection of papers on a selected topic drawn from a variety of sources.

- Health Care Financing Status Report: Research and Demonstrations in Health Care Financing (Red Series)--Basic information in a brief format on the more than 300 intramural and extramural projects conducted by HCFA to examine program expenditures as they relate to reimbursement, coverage, eligibility, and management alternatives under Medicare and Medicaid.

- Health Care Financing Notes (Black-on-White Series)--Brief reports that present either data highlights on various aspects of the Medicare and Medicaid programs or summary information on health care financing topics of special interest.

- Health Care Financing Project Reports (Black-on-Blue Series)--Brief reports on individual research and demonstration projects that provide an overview of the project and major findings or results and include information on obtaining related publications.

- Health Care Financing Review (Green Quarterly plus Annual Supplement)--HCFA's research journal. It focuses on research, demonstrations, and statistical findings related to health care financing. The journal includes trends data that highlight economic developments in the health care sector, as well as announcements of new HCFA research publications and projects.

Additional information on the research publications program and the availability of various reports may be obtained from ORD Publications, Room 2-E-6, Oak Meadows Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

PART A INTERMEDIARIES
TREND DATA AND INDICES
BENEFITS

FY	Benefits Paid (M)	Benefits Paid per Bill	Percent Administrative Cost to Beneficiary Benefits (Including Audit)
80	$25,238,000	$634.29	0.9
81	$30,703,700	$721.76	0.8
82	$36,590,600	$803.28	0.6
83	$40,207,500	$825.80	0.7
84	$44,617,113	$888.50	0.7

INDICES (FY 1980 AS 100 PERCENT)

80	100.0	100.0	100.0
81	121.7	113.8	88.9
82	145.0	126.6	66.7
83	159.3	130.2	77.8
84	176.8	140.1	77.8

PART B CARRIERS

FY 1980 Through FY 1984

The following tables contain significant workload, administrative cost, average manpower, and benefit payment data reflecting the combined performance of all Part B carriers from fiscal years 1980 through 1984.

During the period, the annual workload rose a total of 47.5 percent over the base, while total administrative costs rose only 32.6 percent. In terms of unit cost for processing claims, the decrease from $2.61 to $2.30 is 11.9 percent. Contributing to the reduced cost of processing a claim, in addition to expanded use of data processing equipment and improved procedures, are the increased use of facilities management subcontracts, fixed price contracts, and electronic submission of claims.

PART B CARRIERS
TREND DATA AND INDICES

Workload and Cost

FY	Claims Processed	Administrative Cost	Total Claims Unit Cost
80	152,312,600	$389,043,300	$2.61
81	169,541,700	$450,537,700	$2.66
82	185,769,600	$458,819,500	$2.47
83	204,048,800	$485,833,300	$2.38
84	224,676,923	$515,833,214	$2.30

Indices (FY 80 as 100 percent)

80	100.0	100.0	100.0
81	111.3	115.8	101.9
82	122.0	117.9	94.6
83	134.0	124.9	91.2
84	147.5	132.6	88.1

PART B CARRIERS
BENEFITS EXCLUDING PSRO AND HMO

FY	Benefits Paid (M)	Benefits Paid per Bill	Percent Administrative Cost to Beneficiary Benefits
80	$ 7,798,407	$51.20	5.1
81	$ 9,388,767	$55.38	4.8
82	$11,186,164	$60.20	4.1
83	$13,674,657	$67.02	3.6
84	$15,280,366	$68.01	3.4

INDICES (FY 1980 AS 100 PERCENT)

80	100.0	100.0	100.0
81	120.4	108.2	94.1
82	143.4	117.6	80.4
83	175.4	130.9	70.6
84	195.0	132.8	66.7

NATIONAL HEALTH CARE/SOURCE OF FUNDS

	Calendar Year				
	1965	1970	1975	1980	1984
Total (billions)	$41.9	$75.0	$132.7	$248.1	$390.2
	Percentage Distribution				
Total	100.0	100.0	100.0	100.0	100.0
Private Funds	73.8	63.0	57.5	57.6	59.1
Direct Patient Payments	44.1	35.3	28.7	25.4	25.1
Private Health Insurance	23.9	22.5	25.0	29.3	31.1
Philanthropy/In-Plant	5.8	5.1	3.8	2.9	2.9
Federal Government	13.2	23.6	27.9	28.6	28.6
Medicare	--	10.0	12.3	14.8	16.5
Federal Medicaid	--	4.0	6.0	5.8	5.3
Other Federal	13.2	9.6	9.7	8.0	6.8
State/Local Government	13.0	13.5	14.5	13.8	12.3
State Medicaid	--	3.3	4.7	4.8	4.5
Other State/Local	13.0	10.2	9.9	8.9	7.7

Source: HCFA/OACT

MEDICARE PERSONS SERVED/TYPE OF SERVICE - CY 1984

	Aged		Disabled	
	Persons Served[1] (in thousands)	Served per 1,000 Enrollees	Persons Served[1] (in thousands)	Served per 1,000 Enrollees
Hospital and/or Supplementary Medical Insurance	18,904	686	1,845	639
Hospital Insurance	6,496	240	700	243
Inpatient Hospital	6,195	228	674	234
Skilled Nursing Facility	290	11	9	3
Home Health Agency	1,398	52	100	35
Supplementary Medical Insurance	18,706	699	1,812	684
Physician and Other Medical	18,128	677	1,721	649
Outpatient	8,743	327	1,029	388
Home Health Agency	24	1	2/	-

1/ Medicare enrollees who received a covered service for which: 1) Medicare Trust Fund payments were made and 2) bills were received and processed in HCFA Central Office.

2/ Less than 500.

Source: HCFA/BDMS

PERSONAL HEALTH CARE/PAYMENT SOURCE

	Calendar Year				
	1965	1970	1975	1980	1984
Total (billions)	$35.9	$65.4	$117.1	$219.7	$341.1
	Percentage Distribution				
Total	100.0	100.0	100.0	100.0	100.0
Private Funds	78.0	65.7	60.5	60.6	60.7
Direct Patient Payments	51.6	40.5	32.5	28.7	28.7
Private Health Insurance	24.2	23.4	26.7	30.7	30.7
Other	2.2	1.7	1.3	1.2	1.3
Public Funds	22.0	34.3	39.5	39.4	39.3
Federal	10.1	22.2	26.8	28.4	29.6
State and Local	11.9	12.1	12.7	10.9	9.7

Source: HCFA/OACT

INCOMES AND OUTLAYS OF THE MEDICARE TRUST FUNDS
(in billions)

INCOME

Fiscal Year	HI	SMI	Total
1979	$21.9	$9.8	$31.7
1980	25.4	10.3	35.7
1981	32.9	12.4	45.3
1982	37.6	17.6	55.2
1983	43.9	19.1	63.0
1984	45.6	22.5	68.1

OUTLAYS

Fiscal Year	HI	SMI	Total
1979	$20.3	$8.8	$29.1
1980	24.3	10.7	35.0
1981	29.3	13.2	42.5
1982	34.9	15.6	50.5
1983	38.6	18.3	56.9
1984	42.1	20.4	62.5

Excludes inter-trust fund borrowing.
Outlays include benefit payments and administrative expenses.

MEDICARE BENEFIT PAYMENTS
(in millions)

	1984	1985 (est)	Percent Change
Hospital Insurance			
Total	41,461	47,710	15.1%
Inpatient Hospital	39,085	44,885	14.8%
Skilled Nursing Facility	526	581	10.5%
Home Health Agency	1,848	2,229	20.6%
Hospice	2	15	650.0%
Supplementary Medical Insurance			
Total	19,473	21,808	12.0%
Physician and Part B Suppliers	15,449	17,279	11.8%
Outpatient	3,530	3,910	10.8%
HHA-B	29	48	65.5%
GPPPs	465	571	22.8%

TOTAL HOSPITAL AND SUPPLEMENTARY MEDICAL INSURANCE ENROLLEES INCREASE TO ALMOST 32 MILLION

July 1	HI &/or SMI	HI	SMI
	Number of Enrollees (in millions)		
1984	30.5	30.0	29.4
1980	28.5	28.1	27.4
1975	25.0	24.6	23.9
1970	20.5	20.4	19.6
1966	19.1	19.1	17.7

Type of Coverage	1984	1985 (est)	Percent Change
	Number of Enrollees (in thousands)		
HI &/or SMI			
Aged	27,571	28,176	2.2%
Disabled	2,855	2,876	0.7%
ESRD Only	30	31	4.0%
Total	30,455	31,083	2.1%
HI			
Aged	27,112	27,683	2.1%
Disabled	2,855	2,876	0.7%
ESRD Only	30	31	4.0%
Total	29,996	30,589	2.0%
SMI			
Aged	26,764	27,311	2.0%
Disabled	2,624	2,649	1.0%
ESRD Only	28	29	3.8%
Total	29,415	29,989	1.9%

MEDICARE: Number of Participating Facilities by Type of Facility, Selected Years, 1967-1984
Rapid Growth in Long-Term Care Facilities, SNFs, and HHAs, Has Occurred in Recent Years

Type of Facility	1967	1975	1980	1983	1984
Hospitals	6,829	6,770	6,736	6,687	6,676
Skilled Nursing Facilities	4,405	3,932	5,155	5,760	6,183
Home Health Agencies	1,890	2,290	3,012	4,235	5,237
Comprehensive Outpatient Rehabilitation Facilities	—	—	—	43	61
End-Stage Renal Disease Facilities	—	800	1,054	1,308	1,368
Ambulatory Surgical Centers	—	—	—	155	253
Hospices	—	—	—	76	159
Rural Health Clinics	—	—	403	423	432

CHAPTER VII. END-STAGE RENAL DISEASE PROGRAM (CALENDAR YEAR 1984)

INTRODUCTION

The End-Stage Renal Disease (ESRD) part of this report is required by Section 1881(g) of the Social Security Act and provides the 15 specific data items enumerated therein. It covers activities in calendar year 1984 related to the care of ESRD patients and includes information on the number of patients utilizing the various forms of treatment, the costs involved, discussions of cost-savings experiments, and basic kidney research conducted during the year.

The total dialysis population increased by 9.0 percent in 1984, to 78,483 from 71,987 in 1983. The home dialysis population increased by 11.7 percent, to 15,238 from 13,645 in 1983. This was due largely to the growth of continuous ambulatory peritoneal dialysis (CAPD) from 8,532 patients in 1983 to 9,995 in 1984. CAPD now accounts for 65.6 percent of all home patients. At the end of 1984, the home dialysis population accounted for 19.4 percent of the total dialysis population, a net increase of 0.5 percent over 1983. Table 1 shows the number of patients by treatment setting and type for 1983 and 1984.

The number of transplants performed increased by 14.0 percent in 1984, to 6,968 from 6,112 in 1983. Patients receiving transplants in 1984 accounted for 7.1 percent of the total ESRD population, a net decrease of 1.4 percent from 1983. The percentage of total transplants performed with kidneys from living, related donors decreased 4.5 percent from 1983 figures, while cadaveric (CAD) transplants increased 21.6 percent. Table 2 shows the number of transplants performed for calendar years 1983 and 1984, by type of donor.

In 1984, total expenditures for services were more than $1.9 billion, based on bills posted as of September 30, 1985 (see Table 3). This figure will increase as bills continue to be posted. Average payment rates per treatment were $130.41 in hospital-based facilities and $125.59 in independent facilities. This dual-rate prospective payment system excludes physicians' fees. A monthly capitation payment (MCP) system has been used to pay physicians for their ESRD-related professional services. The average kidney acquisition charge was $11,867 for a living-related-donor kidney and $11,155 for a cadaveric kidney. The average estimated kidney acquisition costs were $9,752 and $9,398, respectively. The average estimated cost for a transplant was $30,705, excluding physicians' services.

Table 1. Dialysis Treatment Modalities

Dialysis Type and Setting		Number of Patients as of: 12/31/83	12/31/84
In-Unit Staff-Assisted Hemodialysis		55,554	60,563
In-Unit Staff-Assisted Peritoneal Dialysis		742	584
In-Unit Self-Hemodialysis		1,475	1,611
In-Unit Self-Peritoneal Dialysis		3	6
Home Hemodialysis		4,323	4,125
Home Peritoneal Dialysis		790	259
Continuous Ambulatory Peritoneal Dialysis		8,532	9,995
Continuous Cyclic Peritoneal Dialysis		379	859
Self-Dialysis Training:	Hemodialysis	33	288
	Peritoneal	156	13
	CAPD		163
	CCPD		17
Total Dialysis Patients		71,987	78,483

Source: ESRD Facility Survey Tables, HCFA

Table 2. Renal Transplants

Type of Donor	1983	1984
Living	1,784	1,704
Cadaveric	4,328	5,264
Total	6,112	6,968

Source: ESRD Facility Survey Tables, HCFA

Table 3. Reimbursement

Type of Payment	Amount (Millions)*
Inpatient	$ 695.9
Outpatient	831.5
Physician/Supplier	376.0
Home Health/Skilled Nursing Facility	13.2
Total	$1916.6

*Not Final Figures - Bills posted through September 30, 1985

Source: Weekly Health Insurance Merge (WHIM) Record, HCFA

Table 4 gives a breakdown of the number of Medicare facilities approved to provide maintenance dialysis services to ESRD patients as of December 31, 1984. Figure 1 shows ESRD program growth from 1974 through 1984.

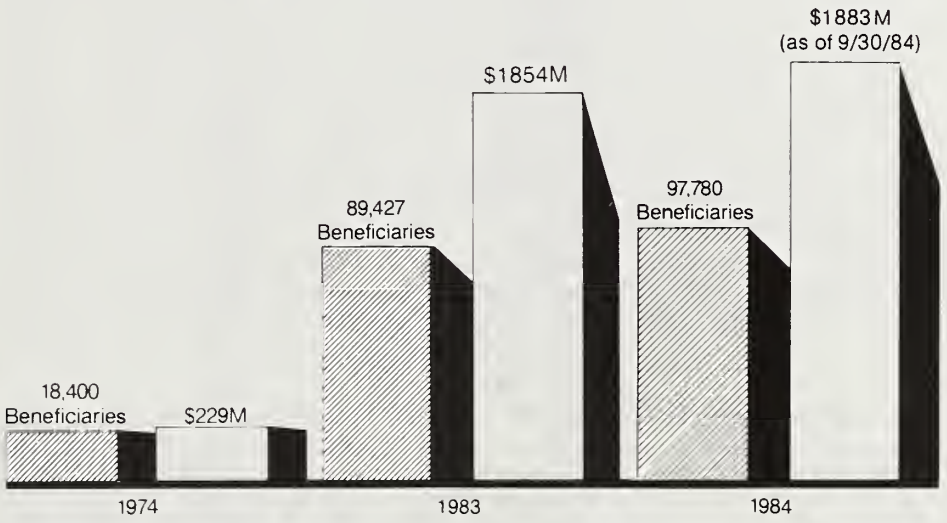
Table 4. Renal Facilities

Total	Profit			Non-Profit		
	Hospitals	Free-Standing Facilities	Hospital Satellites	Hospitals	Free-Standing Facilities	Hospital Satellites
1368	13	529	2	649	139	36

Source: National Listing of Providers Furnishing Kidney Dialysis and Transplant Services, HCFA

Figure 1

ESRD Program Growth



DATA COLLECTION

Information concerning the number of patients in the various treatment modalities and the number of transplants performed was gathered through the End-Stage Renal Disease Facility Survey, which is completed annually by Medicare providers approved to provide renal services.

A total of 1,314 facilities that perform some form of maintenance dialysis and 169 hospitals that perform kidney transplants were requested to complete a Facility Survey (see Table 5); all responded.

Table 5. ESRD Facilities Surveyed and Reporting by State

STATE	DIALYSIS FACILITIES SURVEYED AND REPORTING	TRANSPLANT FACILITIES SURVEYED AND REPORTING
Alabama	25	2
Alaska	1	0
Arizona	20	3
Arkansas	18	2
California	151	13
Colorado	12	1
Connecticut	16	2
Delaware	3	0
Washington, D.C.	14	5
Florida	85	4
Georgia	44	4
Hawaii	7	1
Idaho	4	0
Illinois	63	7
Indiana	13	2
Iowa	10	2
Kansas	6	2
Kentucky	16	2
Louisiana	44	6
Maine	4	1
Maryland	26	3
Massachusetts	25	8
Michigan	38	10
Minnesota	16	3
Mississippi	22	1
Missouri	31	8
Montana	4	0
Nebraska	9	2
Nevada	3	0
New Hampshire	4	0
New Jersey	27	3
New Mexico	12	1
New York	100	13
North Carolina	21	5
North Dakota	4	0
Ohio	42	10
Oklahoma	23	4
Oregon	9	1
Pennsylvania	81	8
Puerto Rico	16	2
Rhode Island	5	0
South Carolina	21	1
South Dakota	6	0
Tennessee	30	2
Texas	75	9
Utah	14	3
Vermont	1	1
Virgin Islands	2	1
Virginia	44	4
Washington	13	5
West Virginia	9	0
Wisconsin	21	2
Wyoming	1	0
American Samoa	1	0
Guam	1	0
Mariana Islands	1	0
TOTALS	1,314	169

Source: ESRD Medical Information System 1984 Facility Surveys

The number of facilities surveyed does not equal the total number of ESRD-certified facilities in the country. Some ESRD hospitals were not considered because they provide only backup dialysis on an acute basis, rather than routine outpatient maintenance dialysis. Other facilities were so recently certified that there was not sufficient time to include them.

The data delineate totals for all ESRD patients. They are not differentiated between patients entitled to Medicare and those who are not, within the various treatment modalities.

Although we have no data to indicate definitely what portion of the patients in any particular treatment modality received Medicare benefits, the Facility Survey indicates that at the end of 1984, 88.25 percent of all patients were entitled to Medicare, 5.39 percent had applications pending, and 6.37 percent were not Medicare eligible.

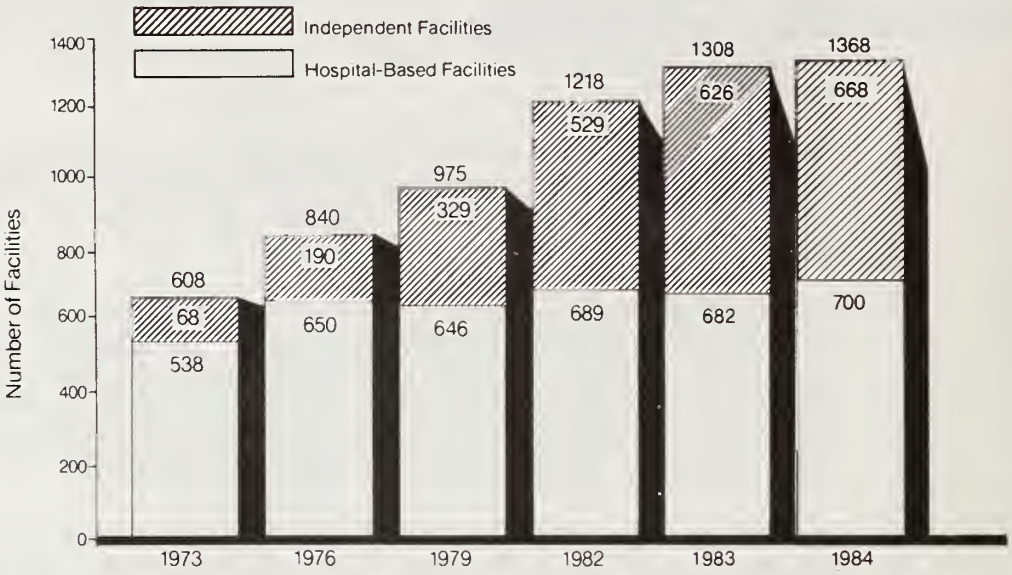
ESRD FACILITY PROFILE

As of December 1984, 1,368 hospitals and facilities were approved to furnish dialysis and transplantation services. Of these, 700 were hospital-based and 668 non-hospital-based. Of the hospital-based facilities, 25 provided transplantation services only, 145 provided both dialysis and transplantation, 477 provided only dialysis services, and 53 provided acute inpatient care dialysis only. There were 170 hospitals approved as ESRD transplant centers. The number of certified facilities increased by approximately 5 percent. There was an increase of 18 hospital-based facilities and 42 non-hospital-based facilities. The number of approved dialysis stations increased by approximately 7.0 percent, to 1,088. Figure 2 shows the growth in the number of certified ESRD facilities from 1973 through 1984. Figures 3, 4, and 5 provide additional information on the geographic distribution and ownership of ESRD facilities.

Each approved dialysis facility is certified to provide any of a variety of specialized services. These services include staff-assisted dialysis, home or self-dialysis training, and CAPD training. Over 66 percent (904) of the approved facilities are certified to provide some type of home self-dialysis training, and approximately 18.6 percent (255) are approved to provide incenter self-care dialysis.

Figure 2

Number of Certified ESRD Facilities*

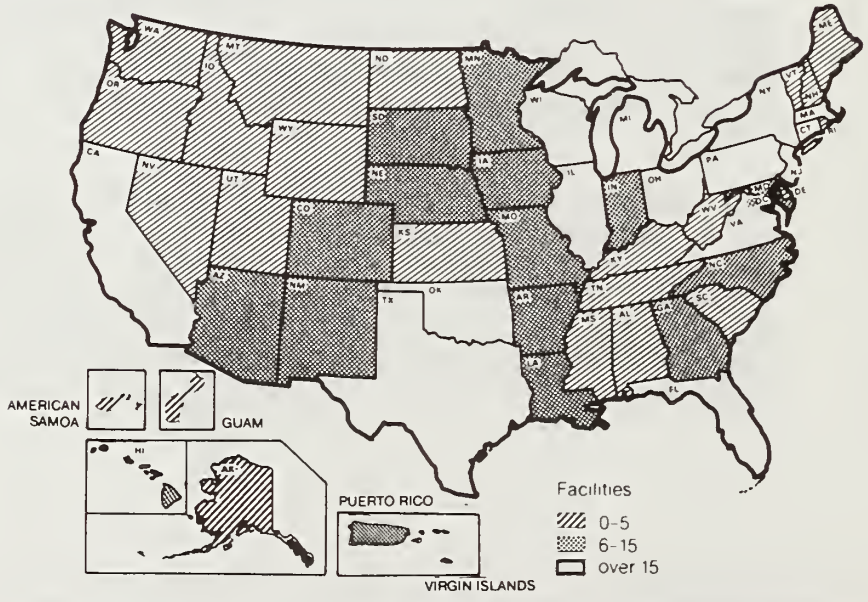


SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1985—HCFA

*This includes all ESRD Medicare approved facilities, not just those providing outpatient maintenance dialysis

Figure 3

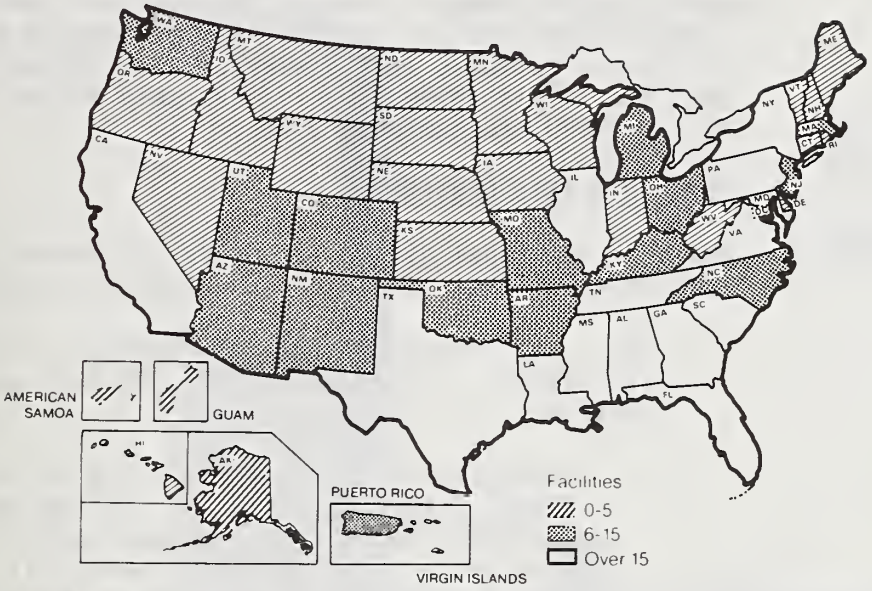
Dialysis Facilities, Hospital—1984



SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1985—HCFA

Figure 4.

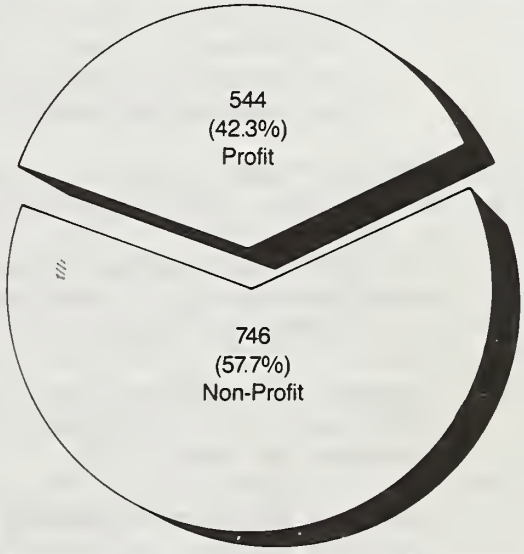
Dialysis Facilities, Independent—1984



Source: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1985—HCFA

Figure 5

Type of Ownership—Profit vs. Non-Profit, 1290 ESRD Dialysis Providers, 1984



SOURCE The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services January 1985—HCFA

MINIMUM UTILIZATION RATES

All approved ESRD facilities are required to meet minimum utilization rates (MURs). Regulations specify the MURs for which a facility will receive either an unconditional or conditional status. However, regulations permit an exception to the MUR for a facility determined not to have sufficient patients in its service area to meet the MUR, if the facility's absence would adversely affect the achievement of ESRD program objectives.

RENAL DIALYSIS CENTERS

The MURs for renal dialysis centers performing greater than 20 percent of their dialyses on outpatients are:

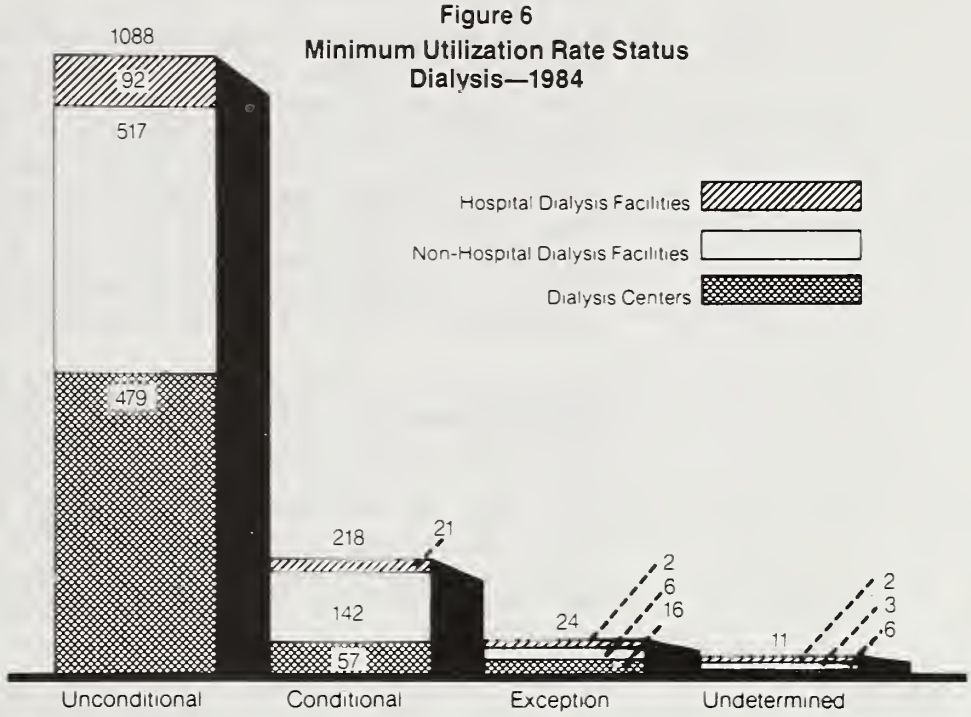
- For any facility located within a metropolitan statistical area (MSA) of 500,000 population or greater:
  - -- Unconditional status--Six or more dialysis stations with performance of an average of 4.5 or more dialyses per station per week.
  - -- Conditional status--Six or more dialysis stations with performance of an average of between 4.0 and 4.5 dialyses per station per week; four or six dialysis stations with performance of an average of 4.5 or more dialyses per station per week.
- For any facility located in an MSA of less than 500,000 population, or in an area not included in an MSA:
  - -- Unconditional status--Three or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week.
  - -- Conditional status--Two dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

The MURs for renal dialysis centers performing 20 percent or less of their dialyses on outpatients are:

- Unconditional status--Three or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week.
- Conditional status--Two dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

Figure 6 shows the 1984 MUR status of approved renal dialysis centers and renal dialysis facilities.

Figure 6
Minimum Utilization Rate Status
Dialysis—1984



SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1985—HCFA

TRANSPLANT CENTERS

Transplant centers are grouped according to MUR certification status in Table 6 below. To achieve unconditional certification, a hospital must perform 15 or more transplants per year; for conditional certification, a hospital must perform 7 to 14 transplants per year. A hospital that does not meet conditional or unconditional utilization standards may be granted an exception if it furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under 42 CFR Subpart U. Most hospitals specializing in renal transplantation services for pediatric patients have been able to qualify without an exception; a few have not.

Table 6. Minimum Utilization Rate Status - Transplants

	Total	Unconditional	Conditional	Exception	Undetermined
Transplants	170	120	40	6	4

MINIMUM UTILIZATION RATE STUDY

Under a contract with the Health Care Financing Administration (HCFA), Moshman Associates conducted a study to determine the relationship between utilization rates of ESRD centers and facilities and quality of care. Their analysis was based on a comprehensive review of patients who received care from a sample of 50 dialysis centers and facilities and 50 transplant centers. Patient information was derived from data stored in the ESRD Program Management and Medical Information System and Medicare beneficiary billing information and verified by a series of site visits.

The contractor found no statistically significant relationship between the utilization rate, charges, and quality of care at transplantation centers and dialysis facilities and centers to indicate that larger institutions were more efficient or provided better medical care. Economic efficiency was found to correlate with the utilization rate for dialysis centers and facilities, but the small samples and low level of the correlation precluded any statistical significance.

DIALYSIS

The total number of ESRD patients receiving dialysis continued to grow. As of December 31, 1984, the total dialysis population was 78,483. This represents an increase of 8.3 percent over the 1983 total of 71,987 patients.

PATIENT PROFILE

Table 7 shows the method and setting of treatment for patients on dialysis as of December 31, 1984. Table 8 shows the number and percent increase of dialysis patients using incenter and home dialysis. Figures 7, 8, and 9 provide further information on the number of patients in each treatment setting.

Incenter

The number of patients receiving treatment in facilities rose by 4,903, to 63,245. This was an increase of 7.8 percent over the 1983 figure. However, the proportion of the total dialysis population represented by incenter dialysis patients decreased from 81.0 percent in 1983 to 80.6 percent in 1984.

Of the incenter population, 61,147, or 96.7 percent, were receiving staff-assisted outpatient maintenance dialysis; 1,617, or 2.5 percent, were performing incenter self-dialysis; and 481, or 1.0 percent, were undergoing self-care dialysis training.

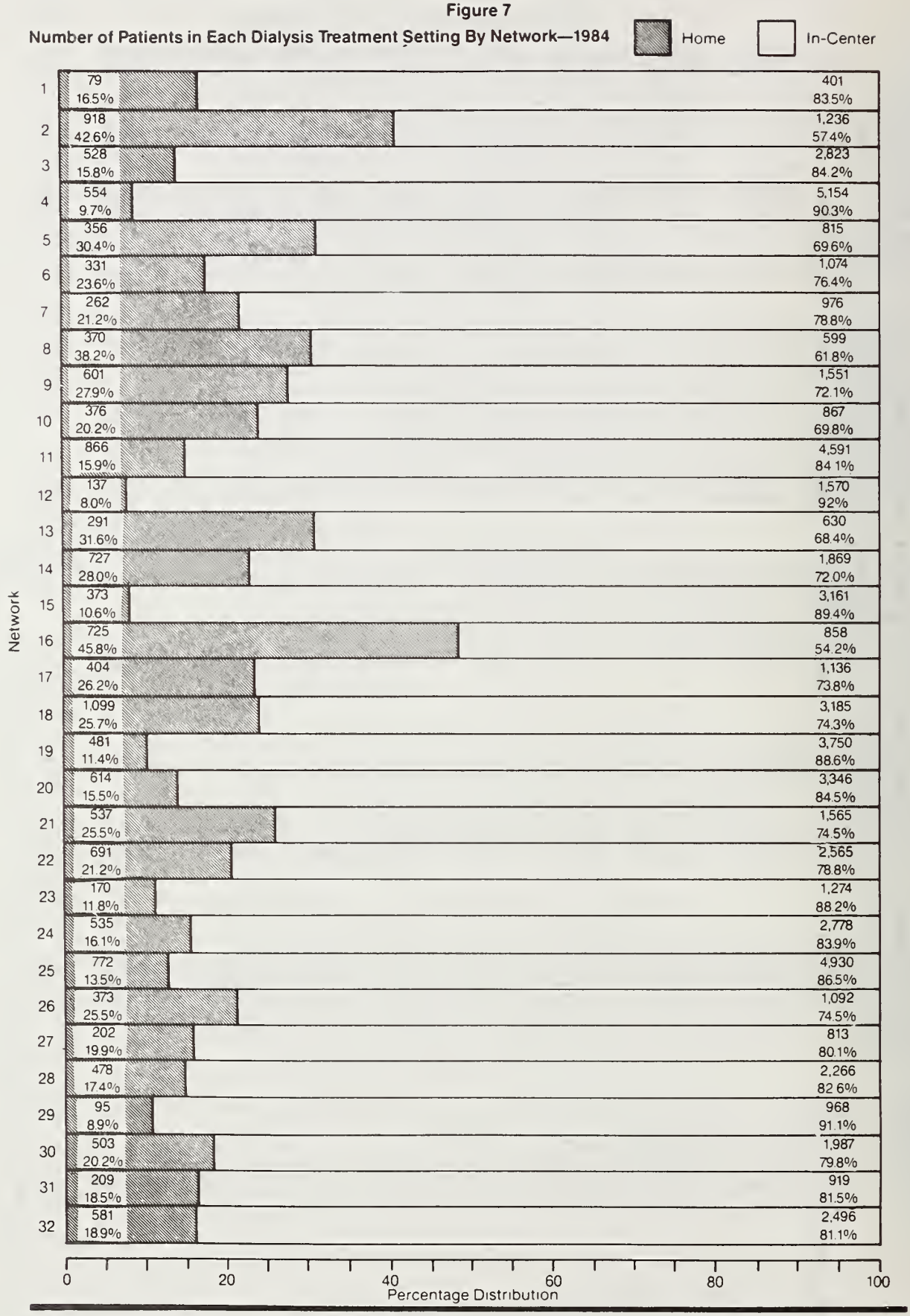
Table 7. Patients Receiving Care of as 12/31/84

ESRD NETWORK	FACILITIES SURVEYED & REPORTING	TOTAL PATIENTS	STAFF-ASSISTED DIALYSIS		SELF-DIALYSIS IN-UNIT		SELF-DIALYSIS TRAINING				HOME PATIENTS			
			HEMO	PERI	HEMO	PERI	HEMO	PERI	CAPD	CCPD	HEMO	PERI	CAPD	CCPD
1	10	480	285	0	108	0	7	0	1	0	30	0	38	11
2	31	2,154	1,188	7	9	0	25	1	5	1	594	9	282	33
3	61	3,351	2,651	0	145	0	26	0	1	0	120	2	382	24
4	93	5,708	5,055	5	56	0	27	0	10	1	78	1	418	57
5	28	1,171	800	0	14	0	0	0	1	0	177	14	165	0
6	32	1,405	1,014	0	53	0	2	0	5	0	44	1	284	2
7	29	1,238	975	1	0	0	0	0	0	0	112	1	124	25
8	19	969	590	5	0	0	4	0	0	0	66	2	256	46
9	37	2,152	1,468	8	57	0	9	0	8	1	184	4	389	24
10	40	1,243	833	26	1	0	7	0	0	0	67	2	277	30
11	75	5,457	4,371	33	141	0	33	0	12	1	206	10	547	103
12	44	1,707	1,516	6	45	0	3	0	0	0	19	2	104	12
13	21	921	570	18	40	0	0	0	2	0	50	3	232	6
14	35	2,596	1,761	48	38	0	14	1	7	0	101	25	586	15
15	61	3,534	2,856	73	216	6	5	0	4	1	71	1	265	36
16	13	1,583	848	0	0	0	4	0	6	0	183	0	542	0
17	25	1,540	1,100	19	11	0	0	0	6	0	54	2	343	5
18	18	4,284	3,156	3	6	0	14	0	5	1	367	82	629	21
19	85	4,231	3,718	5	20	0	1	0	6	0	73	1	380	27
20	66	3,960	3,223	21	69	0	16	0	16	1	125	0	419	70
21	21	2,102	1,548	0	0	0	6	4	6	1	162	16	293	66
22	55	3,256	2,502	32	20	0	1	1	9	0	100	18	523	50
23	26	1,444	1,240	2	29	0	2	0	0	1	25	0	119	26
24	61	3,313	2,655	14	90	0	9	1	9	0	114	17	383	21
25	74	5,702	4,804	75	38	0	7	0	6	0	329	2	434	7
26	27	1,465	970	18	85	0	12	0	6	1	84	8	270	11
27	16	1,015	765	9	24	0	2	0	13	0	23	0	179	0
28	39	2,744	2,185	25	47	0	1	1	5	2	163	10	278	27
29	18	1,063	929	18	19	0	2	0	0	0	59	0	31	5
30	48	2,490	1,920	15	37	0	6	1	8	0	118	4	337	44
31	19	1,128	835	11	66	0	4	0	2	1	56	9	117	27
32	27	3,077	2,232	87	127	0	39	3	4	4	171	13	369	28
TOTAL	1,314	78,483	60,563	584	1,611	6	288	13	163	17	4,125	259	9,995	859

Source: ESRD Medical Information System 1984 Facility Surveys

Figure 7

Number of Patients in Each Dialysis Treatment Setting By Network—1984



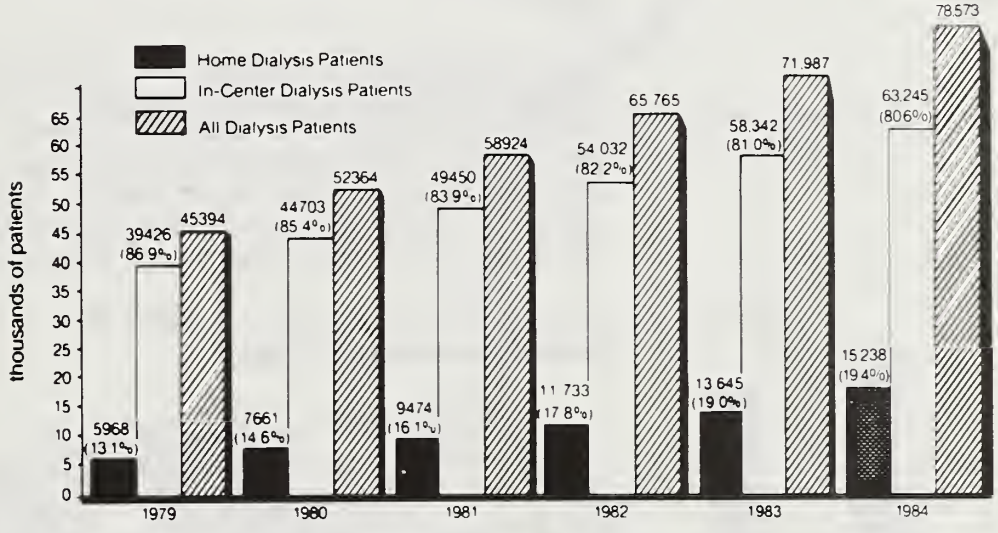
SOURCE: ESRD Medical Information System 1984 Facility Surveys

Table 8. Number and Percent Increase of Dialysis Patients

	1983	1984	Increase	Percent Increase
Total Dialysis Population	71,987	78,483	6,496	8.3%
Incenter Dialysis Population	58,342	63,245	4,903	7.8%
Home Dialysis Population	13,645	15,238	1,593	10.5%

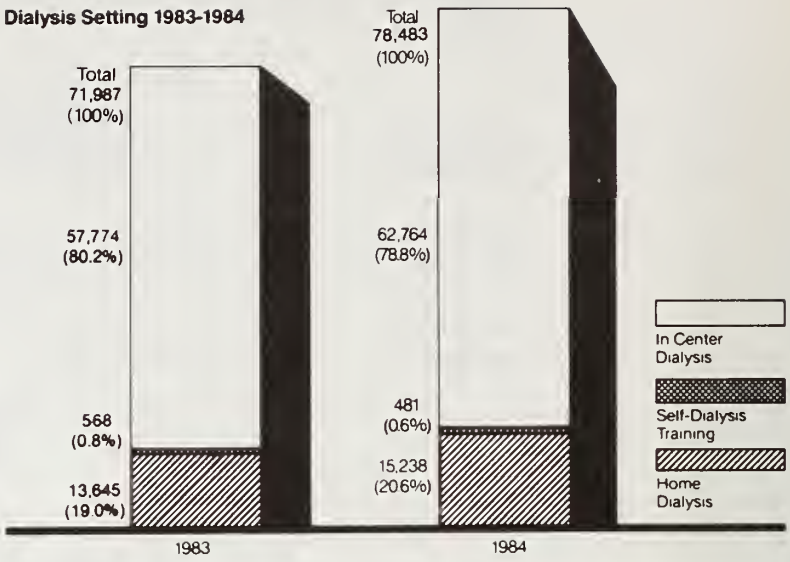
Figure 8

Number of Chronic Dialysis Patients Being Treated by Medicare Certified Suppliers of ESRD Services in the United States by Treatment Setting January 1979-December 1984



SOURCE ESRD Medical Information System 1979 1980 1981 1982 1983 and 1984 Facility Surveys

Figure 9



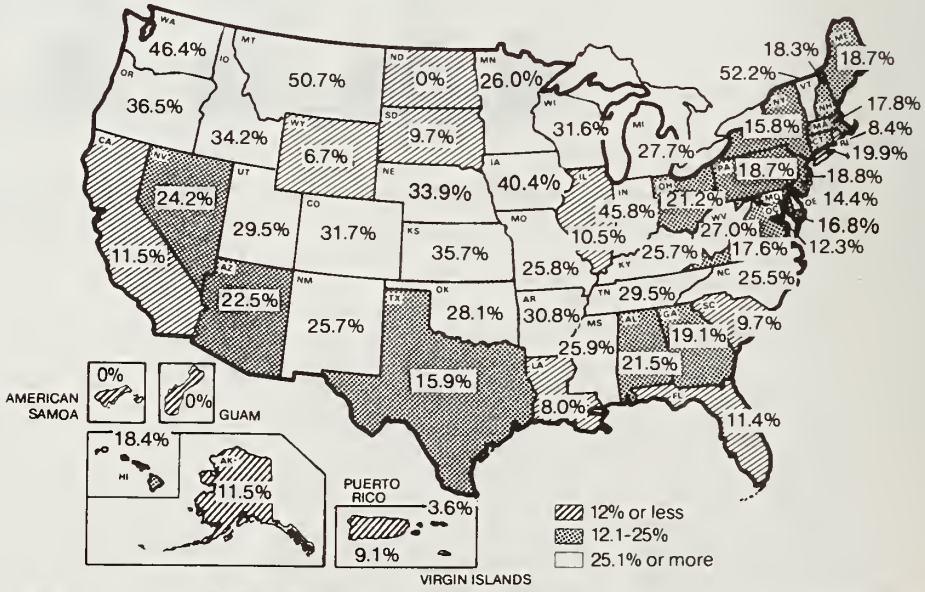
SOURCE ESRD Medical Information System 1983 and 1984 Facility Surveys

Home

The home dialysis population increased by 1,593, an increase of 10.5 percent over 1983. The proportion of patients dialyzing at home is slowly increasing; 15,238 patients, or 19.4 percent of the total dialysis population, were doing so at the end of 1984. In 1983, 19.0 percent of dialysis patients were dialyzing at home. Figure 10 shows the geographic distribution of home-dialysis patients.

Figure 10

Home Dialysis Patients—1984

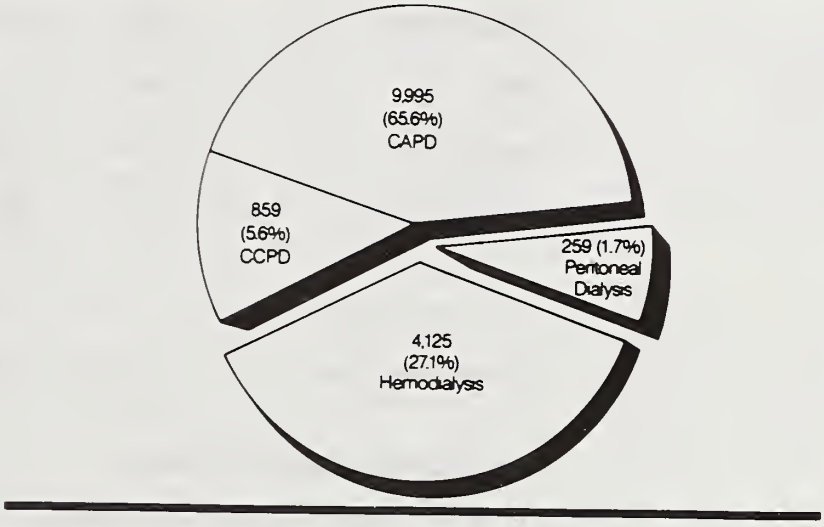


Source: ESRD Medical Information System 1984 Facility Surveys

Of the home dialysis population, 4,125 (27.1 percent) were using hemodialysis; 259 (1.70 percent) were using peritoneal dialysis; 9,995 (65.6 percent) were using continuous ambulatory peritoneal dialysis, and 859 (5.6 percent) were using continuous cyclic peritoneal dialysis (CCPD). Figures 11 and 12 show the breakdown of home dialysis by modality.

Figure 11

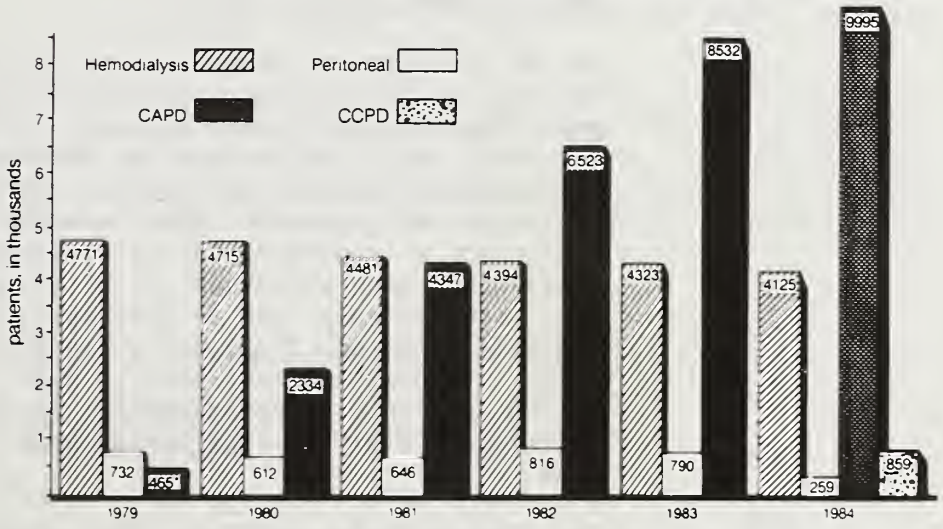
Home Dialysis Modality—1984



SOURCE: ESRD Medical Information System 1984 Facility Surveys.

Figure 12

Home Patient Modalities (Hemodialysis, Peritoneal and CAPD)



SOURCE ESRD Medical Information System 1979, 1980, 1981, 1982, 1983 and 1984 Facility Surveys
*Payment began for CAPD in 9/79. Reportings for CAPD probably misrepresented as "Peritoneal"

Self-Care

Overall, patients performing some form of self-care comprise 22.5 percent of the total dialysis population. Table 9 shows the distribution of patients in self-care over the last 5 years.

Table 9. Annual Distribution of Self-Care Dialysis Patients

Treatment Setting	1980	1981	1982	1983	1984
Home	7,661	9,474	11,733	13,645	15,238
Incenter	781	1,038	1,071	1,478	1,617
Training	521	495	588	568	481
Total:	8,963	11,007	13,392	15,691	17,336
Percent of Total Dialysis Population	17.1%	18.7%	20.4%	21.7%	22.5%

New-Patient Characteristics

Of the 27,081 patients starting a course of dialysis for the first time ever during 1984, 4,071, or 15.0 percent, chose home dialysis and 23,010, or 85.0 percent, chose incenter dialysis. Comparable figures for 1983 were 3,210, or 13.2 percent, of the new starts choosing home dialysis and 21,062, or 86.8 percent, choosing incenter dialysis.

CAPD NATIONAL PATIENT REGISTRY

One of the research objectives of the Chronic Renal Disease Program of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK) continues to be improving the effectiveness but minimizing complications of maintenance dialysis therapies. As part of its effort to evaluate and improve such therapies, the institute has sponsored a registry for patients being maintained on continuous ambulatory peritoneal dialysis. CAPD has been used increasingly as an alternate form of maintenance dialysis since the first early experiences were reported in 1978. Information available to HCFA suggests that nearly 10,000 patients (approximately 15 percent of the U.S. maintenance dialysis population) were maintained on CAPD in 1984.

The United States, unlike other countries, does not have a registry for all ESRD patients on dialysis or kidney transplantation. Because CAPD is a relatively new and

evolving therapy, the National Institutes of Health (NIH) has sponsored the National CAPD Patients Registry to gather information about patient characteristics; primary renal disease; time on dialysis; and selected outcome measures such as complications including peritonitis, exit-site and tunnel infections, catheter replacement, frequency of hospitalizations, transfer to other maintenance dialysis therapies or transplantation, morbidity, and mortality. Data from the registry are made available to clinicians and investigators for the evaluation of CAPD.

The registry began collecting information on a pilot basis in January 1981, at which time data provided by 14 centers were collected and continued for nearly a year. A program to register and follow as many CAPD patients as possible began in late 1981. The registry has followup data on over 11,000 patients maintained on CAPD for varying lengths of time. The data have been collected from over 300 (voluntary) participating centers.

NIADDK plans to continue sponsoring the activities of the National CAPD Patients Registry. However, a joint HCFA-NIADDK initiative is being developed to establish a comprehensive National ESRD Patients Registry. This will use the existing HCFA ESRD data-base capability enhanced with NIH-supported biomedical and biostatistical direction in specified areas of need. It is anticipated that at the time the consolidated patients registry becomes operational, the National CAPD Patients Registry will be incorporated as one section of the overall U.S. ESRD Patients Registry.

TRANSPLANTS

During 1984, 6,968 kidney transplant procedures were performed. This figure reflects cases in which patients received one or more transplants. This represents an increase of 856 transplants, or 14.0 percent, over the 6,112 transplants performed in 1983.

Table 10 shows the range of number of transplants performed, as reported by hospitals, for 1984. Table 11 provides a more detailed breakdown by ESRD network. Figure 13 shows the number of patients awaiting transplants versus the number of transplants performed for the years 1979 through 1984.

Table 10. Numerical Range of Transplants Performed, 1984

Range of Numbers of Transplants Performed	Number of Centers	Percent
0-15	42	24.9
16-50	78	46.2
51-100	36	21.3
100-200	11	6.5
200 or more	2	1.2

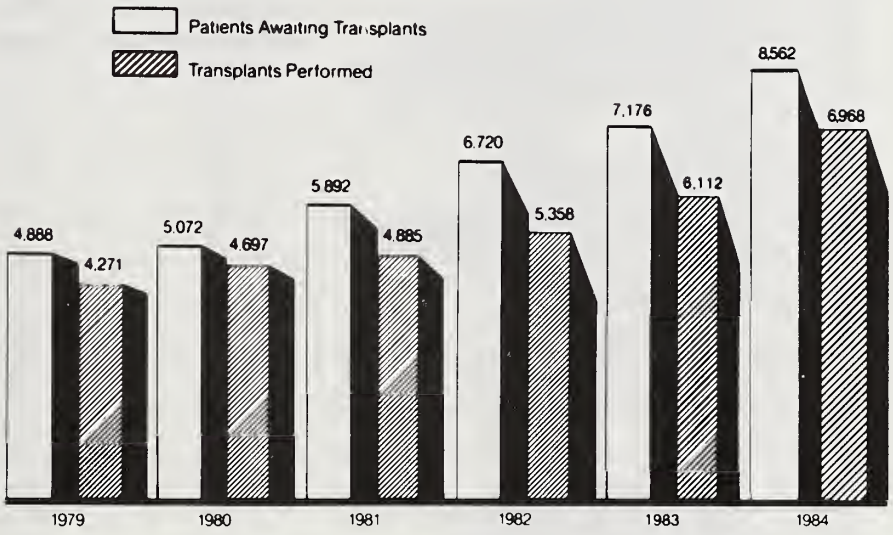
Table 11. ESRD Network Distribution of Transplants Arrayed by Number of Transplants Performed

ESRD NETWORK	FACILITIES SURVEYED-REPORTING	TRANSPLANTS	0 THRU 15		16 THRU 50		51 THRU 100		101 THRU 200		200 OR MORE	
01	1	19	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%
02	6	211	1	16.7%	4	66.7%	0	0.0%	1	16.7%	0	0.0%
03	2	353	0	0.0%	0	0.0%	0	0.0%	1	50.0%	1	50.0%
04	11	455	2	18.2%	6	54.5%	2	18.2%	1	9.1%	0	0.0%
05	4	175	1	25.0%	1	25.0%	2	50.0%	0	0.0%	0	0.0%
06	4	96	2	50.0%	1	25.0%	1	25.0%	0	0.0%	0	0.0%
07	3	299	0	0.0%	0	0.0%	2	66.7%	1	33.3%	0	0.0%
08	4	116	2	50.0%	.	25.0%	1	25.0%	0	0.0%	0	0.0%
09	10	238	3	30.0%	7	70.0%	0	0.0%	0	0.0%	0	0.0%
10	6	104	3	50.0%	3	50.0%	0	0.0%	0	0.0%	0	0.0%
11	9	438	2	22.2%	3	33.3%	2	22.2%	2	22.2%	0	0.0%
12	6	119	4	66.7%	1	16.7%	1	16.7%	0	0.0%	0	0.0%
13	2	237	0	0.0%	0	0.0%	1	50.0%	1	50.0%	0	0.0%
14	10	295	3	30.0%	5	50.0%	2	20.0%	0	0.0%	0	0.0%
15	7	263	2	28.6%	3	42.9%	2	28.6%	0	0.0%	0	0.0%
16	2	112	0	0.0%	1	50.0%	1	50.0%	0	0.0%	0	0.0%
17	6	226	1	16.7%	4	66.7%	1	16.7%	0	0.0%	0	0.0%
18	5	393	0	0.0%	3	60.0%	0	0.0%	2	40.0%	0	0.0%
19	4	238	0	0.0%	1	25.0%	3	75.0%	0	0.0%	0	0.0%
20	5	149	2	40.0%	2	40.0%	1	20.0%	0	0.0%	0	0.0%
21	5	141	0	0.0%	5	100.0%	0	0.0%	0	0.0%	0	0.0%
22	7	579	1	14.3%	2	28.6%	2	28.6%	1	14.3%	1	14.3%
23	5	211	1	20.0%	2	40.0%	2	40.0%	0	0.0%	0	0.0%
24	7	312	1	14.3%	4	57.1%	2	28.6%	0	0.0%	0	0.0%
25	7	356	0	0.0%	3	42.9%	3	42.9%	1	14.3%	0	0.0%
26	6	154	2	33.3%	4	66.7%	0	0.0%	0	0.0%	0	0.0%
27	2	84	0	0.0%	2	100.0%	0	0.0%	0	0.0%	0	0.0%
28	10	258	3	30.0%	5	50.0%	2	20.0%	0	0.0%	0	0.0%
29	3	19	3	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
30	4	98	2	50.0%	1	25.0%	1	25.0%	0	0.0%	0	0.0%
31	3	112	0	0.0%	2	66.7%	1	33.3%	0	0.0%	0	0.0%
32	3	108	1	33.3%	1	33.3%	1	33.3%	0	0.0%	0	0.0%
TOTAL	169	6,968	42	24.9%	78	46.2%	36	21.3%	11	6.5%	2	1.2%

Percentages may not add to 100.0% due to rounding

Figure 13

Patients Awaiting Transplants vs. Transplants Performed



SOURCE: ESRD Medical Information System 1979, 1980, 1981, 1982, 1983 and 1984 Facility Surveys

TRANSPLANT TYPES

The number of living-related-donor transplants in 1984 was 1,704, a decrease of 80 (4.5 percent) such transplants below the 1983 figure of 1,784. Cadaveric transplants, on the other hand, increased by 936 (21.6 percent) to 5,264 from 4,328 in 1983.

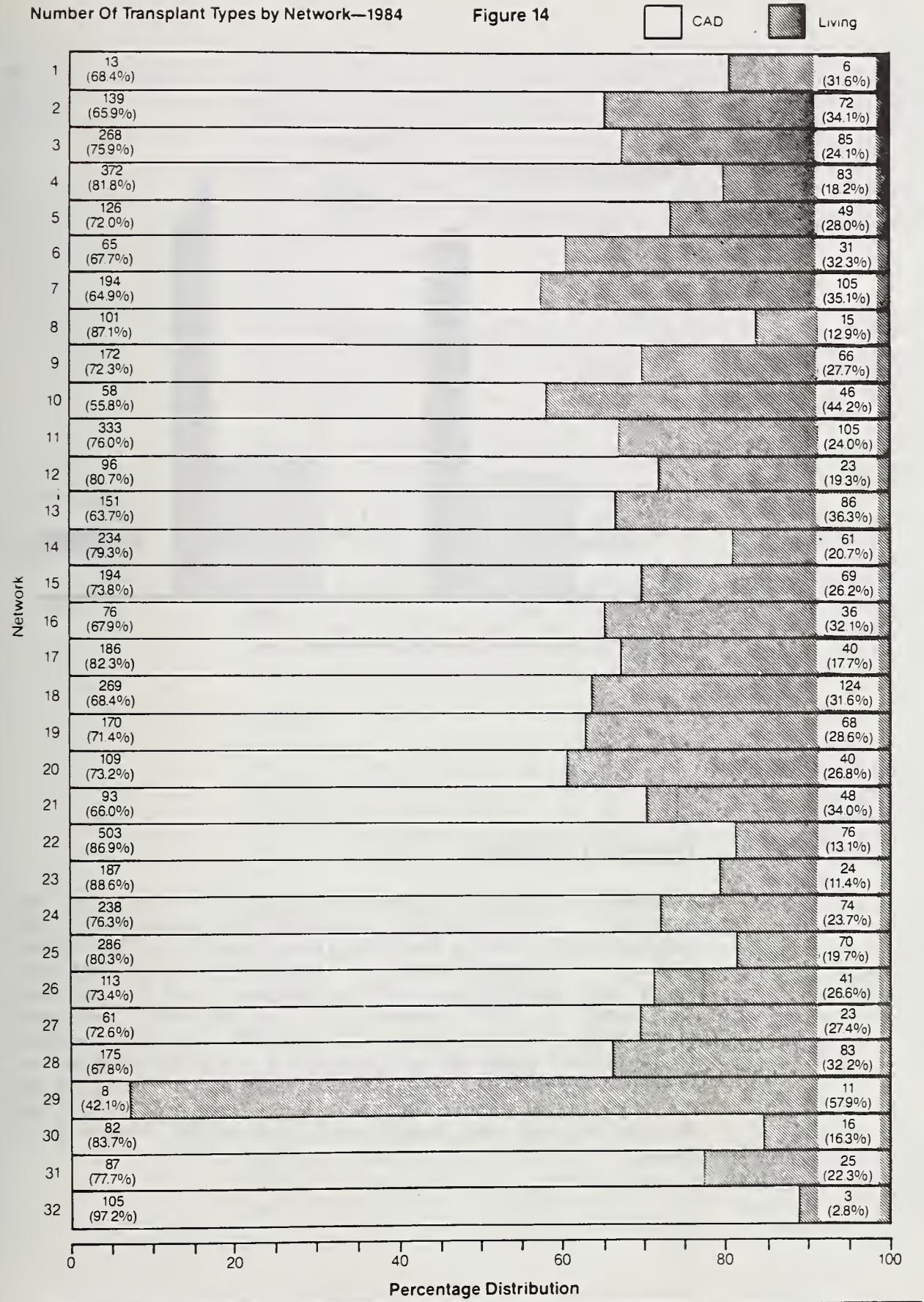
Table 12 shows the number of transplants performed in each State in 1984. Figure 14 shows the number of transplant types by network, and Figure 15 compares transplant types for 1983 and 1984.

Table 12. Transplants Performed During 1984, by State

STATE	FACILITIES SURVEYED & REPORTING	TOTAL PATIENTS	TOTAL TRANSPLANTS	LIVING DONOR	CADAVERIC DONOR
Alabama	2	208	208	73	135
Arizona	3	74	74	26	48
Arkansas	2	24	24	20	4
California	13	808	808	168	640
Colorado	1	48	48	1	47
Connecticut	2	84	84	23	61
District of Columbia	5	211	211	24	187
Florida	4	238	238	68	170
Georgia	4	115	115	35	80
Hawaii	1	19	19	6	13
Illinois	7	263	263	69	194
Indiana	2	111	112	36	76
Iowa	2	89	89	13	76
Kansas	2	73	73	16	57
Kentucky	2	83	83	16	68
Louisiana	6	116	119	23	96
Maine	1	23	23	7	16
Maryland	3	112	112	25	87
Massachusetts	8	216	217	68	149
Michigan	10	295	295	61	234
Minnesota	3	298	299	105	194
Mississippi	1	32	32	1	31
Missouri	8	165	165	50	115
Nebraska	2	27	27	2	25
New Jersey	3	108	108	3	105
New Mexico	1	22	22	5	17
New York	13	508	510	111	399
North Carolina	5	141	141	48	93
Ohio	10	508	515	101	414
Oklahoma	4	80	80	26	54
Oregon	1	107	108	32	76
Pennsylvania	8	504	519	74	445
Puerto Rico	2	10	10	6	4
South Carolina	1	34	34	5	29
Tennessee	2	153	153	50	103
Texas	9	436	438	105	333
Utah	3	125	127	48	79
Vermont	1	18	18	8	10
Virgin Islands	1	9	9	5	4
Virginia	4	98	98	16	82
Washington	5	103	103	40	63
Wisconsin	2	237	237	86	151
TOTAL	169	6,933	6,968	1,704	5,264

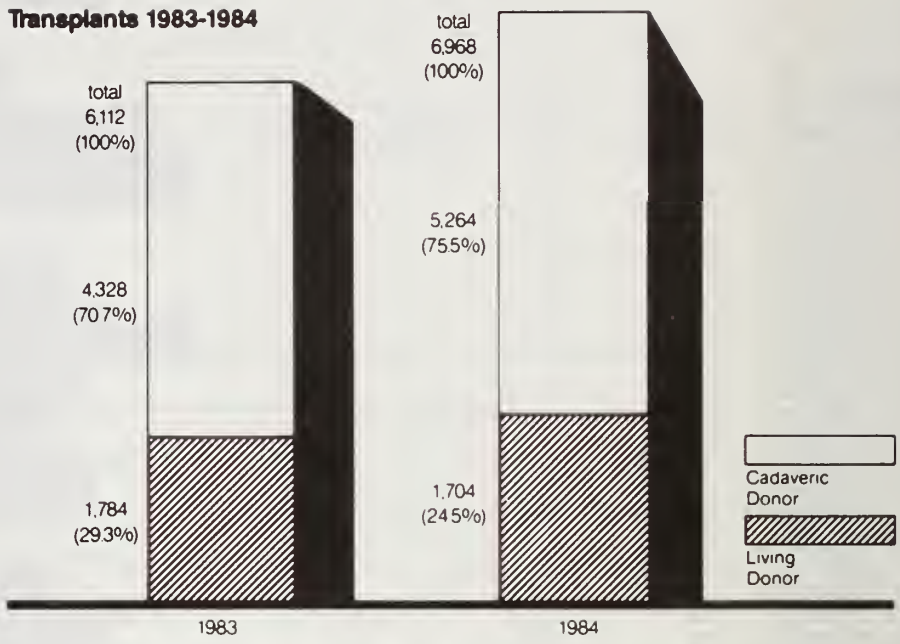
The following States have no renal transplant centers: Alaska, Delaware, Idaho, Montana, Nevada, New Hampshire, North Dakota, Rhode Island, South Dakota, West Virginia, Wyoming, American Samoa, Guam, and the Mariana Islands.

Number Of Transplant Types by Network—1984 Figure 14



SOURCE: ESRD Medical Information System 1984 Facility Surveys

Figure 15



SOURCE ESRD Medical Information System 1983 and 1984 Facility Surveys

TRANSPLANT FAILURES

Although exact information on transplant failures is not available, information collected by HCFA shows that 1,923 patients returned to dialysis from transplantation during 1984. This figure represents 31.4 percent of all patients receiving transplants in 1984, compared to 1,867 patients in 1983, or 30.5 percent of all patients receiving transplants in that year. It should be noted, however, that these figures do not present a complete picture of transplant failures. For example, they do not indicate how many years a transplanted graft functioned before failing. Nor do they indicate transplant failure which resulted in death.

COST OF HOSPITALIZATION FOR ANCILLARY PROBLEMS

For the purposes of this report, ancillary hospitalizations were defined as all hospitalizations other than transplants. This is a necessary simplification, because many hospitalizations are related to the transplant event, either before the actual transplant or afterward, such as rejection episodes. However, it is not possible to identify completely which hospital stays are transplant "related." Therefore, the nontransplant stays of transplant patients are considered to be ancillary hospitalizations.

DATA

The Medicare Provider Analysis and Review File, or MEDPAR, contains discharge records (including diagnostic and procedure coding) for a random 20 percent sample of all Medicare beneficiaries. The basic data for this report were taken from the 1982 MEDPAR sample. Because the sample of stays includes procedure coding, it was possible to determine average charges and length of stay for transplant and nontransplant stays. The 1982 MEDPAR contained a slight shortfall (about 1 percent) at the time of this analysis, so the figures were adjusted upward to approximate costs for 100 percent of stays. Hospital-covered charges and covered days of care were estimated directly from the MEDPAR records. The Medicare prospective payment system (PPS) went into effect on October 1, 1983. Therefore, these data are unaffected by changes in hospital behavior due to this payment method.

RESULTS

Table 13 summarizes the results of this analysis. In 1982, Medicare ESRD patients had a total of 100,051 discharges. Of the total discharges, 57 percent were nonsurgical, 38 percent included a surgical procedure other than transplant, and the remaining 5 percent were for transplants.

Inpatient charges amounted to almost $679 million for this population. Because of the relatively high cost of transplant stays, over one-fifth (22 percent) of all inpatient charges were for transplant stays. Overall, the average charge per stay for the ESRD population in 1982 was $6,786. The average transplant stay had a charge of $30,705, while the average ancillary (i.e., nontransplant) hospital stay had a charge of $5,550. Of the total ancillary stays, the average for surgical stays was $8,655.

Medicare reimbursement is not equal to hospital charges. Applying the national ratio of Medicare reimbursements to charges gives an estimate of the costs to Medicare for ESRD hospitalizations. In 1982, the costs-to-charges ratio was

0.672. That is, Medicare paid hospitals an average of 67.2 percent of charges. For all ESRD patients, estimated Medicare inpatient hospital payments were $456 million in 1982: $101 million for transplants, and $355 million for nontransplant (or ancillary) stays.

As noted earlier, nonsurgical stays comprised 57 percent of all stays, while nontransplant surgical stays were 38 percent of the total. However, due to the higher costs of surgical stays, the nontransplant surgical stays accounted for 49 percent of all reimbursements. The estimated Medicare reimbursement per stay is $4,560 for all discharges, $20,634 for transplants, and $3,729 for all nontransplant stays. Among ancillary stays, nonsurgical stays average $2,335 and surgical stays average $5,816.

Table 13
Charges, Estimated Reimbursement, and Average Length of Stay for Transplant and Nontransplant Hospital Stays: 1982

	All Stays	Transplant Stays	Nontransplant Stays		
			All	Non-Surgical	Surgical
Number of Stays	100,051	4,917	95,135	57,030	38,104
Percent	100%	5%	95%	57%	38%
Charges (in 1,000's)	$ 678,946	$150,976	$527,970	$198,181	$329,789
Percent	100%	22%	78%	29%	49%
Charges Per Stay	6,786	$ 30,705	$ 5,550	$ 3,475	$ 8,655
Estimated Reimbursement (1,000's)	$ 456,252	$101,456	$354,796	$133,177	$221,618
Percent	100%	22%	78%	29%	49%
Estimated Reimbursement Per Stay	$ 4,560	$ 20,634	$ 3,729	$ 2,335	$ 5,816
Covered Days	1,092,034	140,626	951,408	497,972	453,436
Percent	100%	13%	87%	46%*	42%*
Average Length of Stay (Covered Days)	10.9	28.6	10.0	8.7	11.9

*Figures do not add to 87% because of rounding.

SOURCE: 1982 MEDPAR 20 percent sample of hospital stays and ESRD Medical Information System.

KIDNEY ACQUISITION COSTS

Kidney acquisition services are those services necessary to identify potential donors, maintain a registry of patients awaiting transplant, ensure suitability and compatibility of donor and recipient, excise the donor kidney, transport the organ to the transplant hospital, and maintain the viability of the organ until transplantation. Charges for these services are accumulated and billed to Medicare by the hospital which performs the transplant. Costs are estimated from reported kidney acquisition charges.

DONOR TYPE

Data compiled for 146 transplant hospitals indicate that during 1984, the national average kidney acquisition charge for living-related-donor kidneys was $11,867 and for cadaveric-donor kidneys, $11,155. The range and average of kidney acquisition charges by DHHS regions are shown in Tables 14A and 15A. From 1983 to 1984 the national average kidney acquisition charge for living-related-donor kidneys increased $1,802, or 17.90 percent; for cadaveric-donor kidneys, the increase was $1,305, or 13.25 percent.

Using data on the total Medicare cost-to-charge ratio extracted from settled or filed cost reports for each transplant center for the 3 most recent years, it is estimated that the average national kidney acquisition cost for living-related-donor kidneys was $9,752 and for cadaveric-donor kidneys, $9,398. The range and average of estimated kidney acquisition costs by DHHS region are shown in Tables 14B and 15B. From 1983 to 1984, the average estimated national kidney acquisition cost for living-related-donor kidneys increased $1,300, or 15.38 percent, and for cadaveric-donor kidneys, $1,100, or 13.26 percent. It should be noted that the costs derived are based on the arithmetic mean and are not weighted by the number of transplants performed in each hospital.

Table 14A
Kidney Acquisition Charges
Average and Range for Living-Related-
Donor Kidneys for 1984 by Region

REGION	# OF HOSPITALS	HIGH	LOW	AVERAGE
Boston	9	$32,725	$2,000	$13,113
New York	16	28,000	2,400	11,599
Philadelphia	17	30,000	6,500	13,286
Atlanta	21	35,850	4,500	10,649
Chicago	31	20,500	3,250	11,114
Dallas	17	14,000	4,000	8,453
Kansas City	8	23,075	10,900	15,237
Denver	3	12,000	7,000	9,649
San Francisco	15	32,500	5,500	13,870
Seattle	5	15,570	9,150	11,704
National	142	$24,422	$5,520	$11,867

Table 14B
Kidney Acquisition Costs
Average and Range of Estimated Costs for Living-Related-
Donor Kidneys for 1984 by Region

REGION	# OF HOSPITALS	HIGH	LOW	AVERAGE
Boston	9	$23,158	$1,654	$10,442
New York	16	16,274	1,950	8,765
Philadelphia	17	22,725	3,523	11,831
Atlanta	21	28,596	3,278	9,064
Chicago	31	19,085	2,762	8,699
Dallas	17	11,444	3,509	7,164
Kansas City	8	18,254	8,404	13,426
Denver	3	11,527	5,122	7,416
San Francisco	15	25,696	4,098	10,727
Seattle	5	12,379	7,196	9,990
National	142	$18,914	$4,150	$9,752

Source: Medicare Fiscal Intermediaries' Reimbursement Files

Table 15A
Kidney Acquisition Charges
Average and Range for Cadaveric-Donor Kidneys
for 1984 by Region

REGION	# OF HOSPITALS	HIGH	LOW	AVERAGE
Boston	11	$14,175	$8,765	$11,436
New York	15	21,500	2,400	11,493
Philadelphia	18	30,000	5,970	12,126
Atlanta	21	13,925	3,500	9,233
Chicago	31	20,500	2,094	10,774
Dallas	17	10,700	5,500	8,630
Kansas City	9	24,000	8,730	16,225
Denver	3	8,600	4,100	7,082
San Francisco	15	32,500	8,300	13,647
Seattle	5	15,570	9,150	10,904
National	145	$19,147	$5,851	$11,155

Table 15B
Kidney Acquisition Costs
Average and Range of Estimated Costs for Cadaveric-
Donor Kidneys for 1984 by Region

REGION	# OF HOSPITALS	HIGH	LOW	AVERAGE
Boston	11	$12,096	$6,252	$9,225
New York	15	16,274	1,950	10,154
Philadelphia	18	22,725	3,236	10,856
Atlanta	21	13,124	2,549	7,915
Chicago	31	19,085	1,847	8,682
Dallas	17	9,386	4,496	7,819
Kansas City	9	21,920	6,590	14,208
Denver	3	8,261	3,279	5,314
San Francisco	15	25,696	6,462	10,401
Seattle	5	12,379	7,196	9,405
National	145	$16,095	$4,386	$9,398

INDEPENDENT ORGAN PROCUREMENT

Kidney acquisition services are performed for hospitals by independent organ procurement agencies (OPAs). The services provided differ among OPAs and range from providing only placement services to providing all services except medical evaluation of the recipient and living donors. Costs incurred by an OPA are billed to the transplant hospital and become a component of the hospital's kidney acquisition cost; payment is made on a reasonable-cost basis.

There were 36 operational OPAs with kidney acquisition costs during 1984. The cost per kidney by region ranged from $3,949 to $8,451. These figures are estimated and subject to adjustment on final settlement. Cost per kidney varies widely because of the variation in the number of kidney acquisition services performed by individual OPAs.

Data for OPAs were not broken down by type of kidney donor. Table 16 presents OPA data by region; included are the number of operational OPAs by region, viable and nonviable kidneys acquired, total cost, and the average cost per acquisition. Figure 16A shows the regional breakout of the 4,886 kidneys harvested by OPAs in 1984. Figure 16B charts the average cost per acquisition by region for the $36.7 million paid to OPAs for kidney acquisition in 1984.

Table 16
Kidney Acquisition Costs
Reported by Independent Organ Procurement Agencies
by Region for 1984

REGION	NO. OPA'S	TOTAL KIDNEYS	NON VIABLE	NET KIDNEYS	COST	COST PER ACQUISITION
Boston	1	263	53	209	$ 1,462,032	$6,995
New York	3	293	61	232	$ 916,103	$3,949
Philadelphia	5	1992	106	1886	$14,361,459	$7,615
Atlanta	10	898	115	783	$ 6,306,905	$8,055
Chicago	6	696	55	641	$ 4,971,269	$7,755
Dallas	5	403	76	329	$ 2,482,500	$7,546
Kansas City	3	303	28	275	$ 2,252,233	$8,190
Denver		NO ACTIVITY DURING 1984				
San Francisco	2	466	43	423	$ 2,992,815	$7,075
Seattle	1	134	26	108	$ 912,671	$8,451
Total	36	5448	563	4886	$36,657,987	$7,503
Range-Low	1	134	26	108	$ 912,671	$3,949
Range-High	10	1992	115	1886	$14,361,459	$8,451

Note: Data are provided from OPAs' cost reports with fiscal year ending in 1984. (Data may change based on audit.)

Source: Bureau of Eligibility, Reimbursement and Coverage, HCFA

Figure 16 A

Number of I.O.P.A. Kidney Acquisitions for 1984

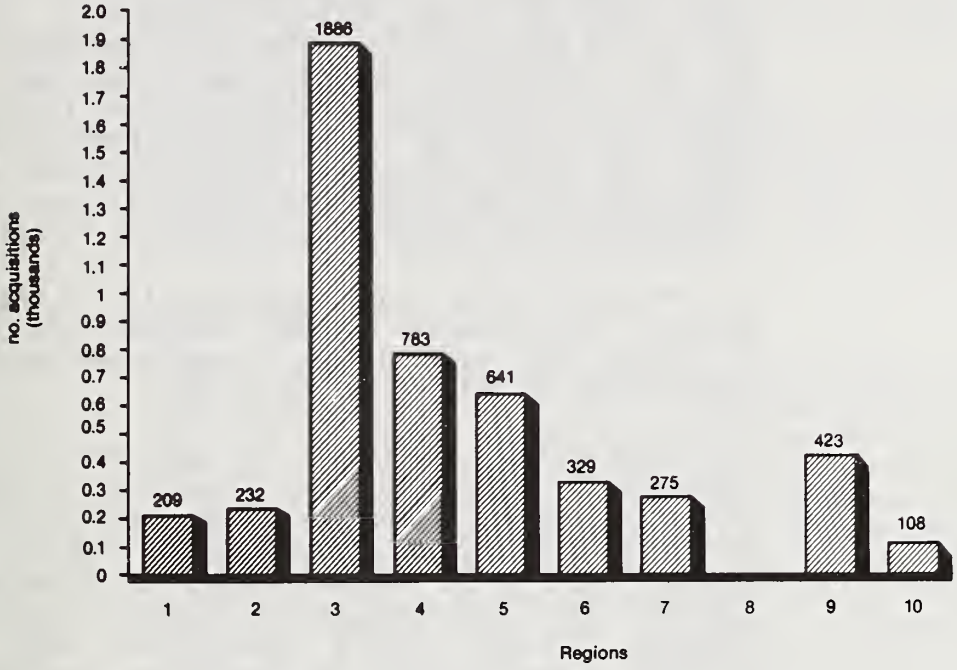
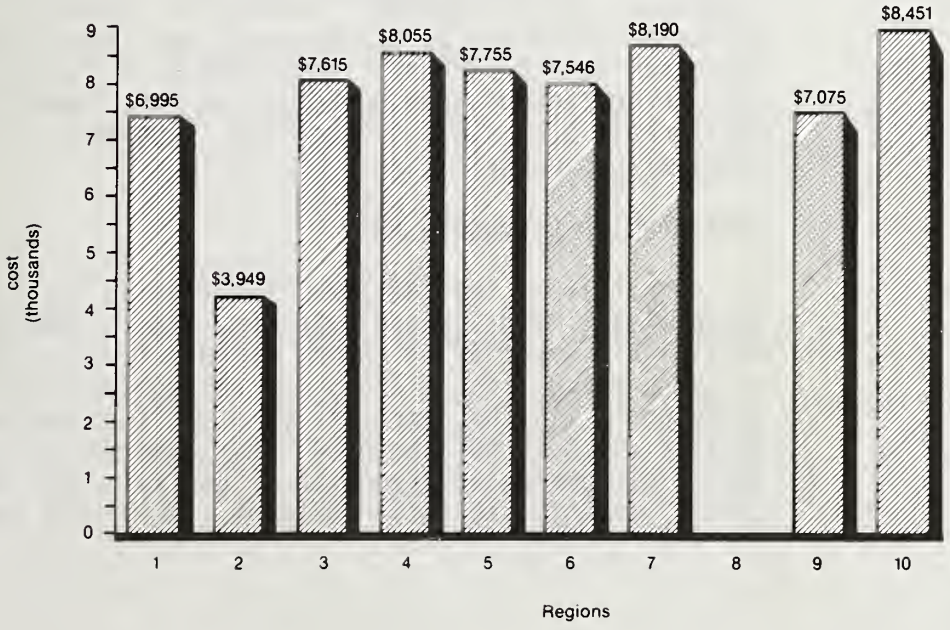


Figure 16 B

I.O.P.A. Cost Per Kidney Acquisition for 1984



MEDICARE PAYMENT RATES

REIMBURSEMENT FOR DIALYSIS AND RELATED SERVICES

The prospective payment system for dialysis (the ESRD composite rate) was in effect for the first full year in 1984. The composite rate, effective August 1, 1983, is a prospective payment system under which two rates are set: one for independent dialysis facilities and a separate, higher rate for hospital-based dialysis facilities. The same rate is paid for infacility and home dialysis. For 1984, the estimated average payment rate was $126.59 per treatment for independent dialysis facilities and $130.59 per treatment for hospital-based dialysis facilities.

An integral part of the composite rate is the number of Medicare beneficiaries on home dialysis. As of December 31, 1984, the total dialysis population increased by 9 percent from 71,987 in 1983 to 78,483.

The home dialysis portion of the total dialysis population increased by 0.4 percent from 19 percent in 1983 to 19.4 percent. This corresponds to a home dialysis population growth of 11.7 percent from 13,645 in 1983 to 15,238 in December 1984, while infacility patients increased by 4,903 patients, or 7.8 percent, with an overall dialysis patient increase of 6,496, or 8.3 percent over 1983. The net increase in home patients was due to the continued growth of continuous ambulatory peritoneal dialysis patients, augmented by the steady growth of continuous cycling peritoneal dialysis home patients. The combined CAPD and CCPD patients now account for 71.2 percent of all home patients.

Among independent dialysis facilities, home patients increased by 17.5 percent while infacility patients increased by 11.5 percent. Similarly, hospital-based home patients increased by 8.1 percent and infacility patients increased by 3.8 percent. Data show a continued decline in the percentage of home hemodialysis and home intermittent peritoneal dialysis patients from independent as well as hospital-based facilities.

Challenge to Composite Rate

In August 1983, the National Association of Patients on Hemodialysis and Transplantation, Inc. (NAPHT), Renal Physicians Association (RPA), and Bio-Medical Applications of Vero Beach, Inc. filed a lawsuit against the Secretary, alleging: (1) the composite rate was too low because some facilities could not increase their home patient population due to circumstances beyond their control; (2) the physicians' monthly capitation payment (MCP) rate was too low

and without a logical basis for the rate-setting methodology; (3) the Secretary illegally abrogated the initial method of physician reimbursement; and (4) the Secretary implemented the ESRD Medicare secondary payer (MSP) provision in a manner that was inconsistent with the statute.

On September 7, 1984, the court filed its final judgment favorable to the Secretary on the issues of setting the composite rate and the physicians' MCP, and favorable to the plaintiffs on the issues of reinstating the initial method of physician reimbursement and revising the implementation of the MSP provision.

Physicians' Services

Since August 1, 1983, all physicians furnishing outpatient maintenance dialysis services have been paid for those services under the monthly capitation payment system. The MCP is a comprehensive monthly payment per patient for almost all physicians' outpatient maintenance-dialysis services furnished during the month. The same rate is paid for patients who dialyze in the facility as for those who dialyze at home. Because home patients require less physician involvement than facility patients, this provides a financial incentive for the increased use of home dialysis. The payment levels under the MCP, which vary by State, range from $144 per month to $220 per month.

Physicians' inpatient dialysis services are paid under either of two methods, depending upon the physician's choice. The first method is to pay under the MCP. The second is to bill separately for all physicians' services furnished during the inpatient stay and prorate the MCP for the same amount of time.

Hepatitis-B Vaccine

Beginning September 1, 1984, Medicare covers hepatitis-B vaccine and its administration when furnished to eligible dialysis patients and certain other high- and intermediate-risk beneficiaries.

EXCEPTION SYSTEM

Reimbursement Exceptions - Pre-Composite Rate

During 1984, HCFA received 89 exception requests (87 hospital-based, 2 independents), responded to 79 exception requests, and had 10 exceptions pending. Of the 79 responses, 52 were returned to the intermediary for further development, 16 were denied, and 11 were approved in part.

Reimbursement Exceptions - Composite Rate

Under the composite rate system, HCFA received 49 exception requests (41 hospital-based, 8 independents), responded to 44, and had 5 pending at the year's end. Of the 44 responses, 21 were returned to the intermediary for further development, 15 were denied, and 8 were approved. Following is a breakdown of the exceptions granted:

Atypical Service Intensity (patient mix)	2
Isolated Essential Facility	2
Training	2
Frequency of Dialysis	2
Educational Costs	0
Extraordinary Circumstance	0
TOTAL	8

TRANSPLANT PROCEDURES

Physicians' renal-transplantation services are not paid under the usual Medicare reasonable-charge methodology used to determine payment for physicians' services. Instead, a comprehensive payment is made for all of the surgeon's services (including the usual pre- and postoperative surgical care) and for immunosuppressant therapy when supervised by the attending transplant surgeon, for a period of 60 days. Additional amounts established on the basis of program experience may be included for other surgery performed concurrently with the transplant operation, such as a splenectomy, or a combination of all of these.

The comprehensive payments are revised annually to the extent permitted by the lesser of:

- Changes in the economic index used to limit prevailing charges for other physicians' services (an increase of 5.85 percent for the period July 1983-June 1984), or

- Changes from one year to the next in the prevailing charges for a unilateral nephrectomy for each of the carrier's localities. This reflects geographical variations in physician charging practices and would also vary on the basis of whether the surgeon performs other surgical procedures at the time of the renal transplantation.

PROJECTED ENROLLMENT AND BENEFIT PAYMENTS

Medicare enrollment for persons with ESRD is projected to increase from 112,400 in FY 86 to about 151,700 through FY 90. Medicare benefit payments for these persons are projected to increase from $2.6 billion to about $4.5

billion for the same period. These changes are the result of the interaction of two factors: population increases, including changes in the mix of treatment modes, and increases in the cost of services. Table 17 shows the projected enrollment and benefit payments on a cash basis through 1990. These projections reflect the cost effects of the newest ESRD regulations (i.e., the dual composite rate and the ESRD secondary payer regulation).

Table 17. Estimated Enrollment and Aggregate Payments

Fiscal Year	Average Annual Enrollment (thousands)	Total Benefit Payments (millions)
1986	112.4	$2,662
1987	121.4	3,050
1988	130.8	3,480
1989	140.8	3,970
1990	151.7	4,510

Table 18 shows the projected additional income estimated to be generated by the ESRD secondary payer regulation.

Table 18. Estimated Income to Medicare Generated by ESRD Secondary Payer Regulation

Fiscal Year	Income Generated (in millions)
1986	$35
1987	45
1988	55
1989	60
1990	65

Source: Office of the Actuary, HCFA

PATIENT SURVIVAL

An analysis was conducted to evaluate program experience with respect to patient survival on dialysis. All Medicare enrollees with renal failure (first date of dialysis) occurring between January 1, 1980, and December 31, 1984, were included in the analysis.

DATA

Computation of survival rates for dialysis patients requires a date of renal onset and a date of death. Dates of death were taken from the master beneficiary records maintained for all Medicare beneficiaries. Onset of renal failure was defined as the date of first dialysis indicated in the patient medical evidence record (HCFA-2728), the outpatient dialysis record (HCFA-1483), or the entitlement records.

Survival rates were calculated using a standard actuarial modified life-table analysis. The number of deaths occurring among new enrollees during each year was divided by the total number of new ESRD enrollees that year to obtain the survival rate. Because Medicare entitlement occurs for many persons following a 90-day waiting period, survival probabilities were computed beginning from the end of this waiting period. Patients were followed from this start date until death, kidney transplant, or 365 days from the start date, whichever came first.

RESULTS

Life-Table Analyses

Table 19 presents the results of the survival analysis for all Medicare beneficiaries with ESRD treated by dialysis. In 1980 and 1981, patient survival at 1 year was 82 percent. This declined to 81 percent in 1982. There was a further decline to 78 percent in 1983, followed by a slight rise to 79 percent in 1984. This pattern occurred across sex, race, and diagnostic groups.

Part of the change in mortality over this period can be explained by the changing age distribution. In 1980, persons aged 61 and over accounted for 37 percent of all new enrollees. By 1984, these age groups accounted for 44 percent of the new enrollees. From 1980 to 1984, there was a 33 percent increase in new enrollees aged 61 to 70 (4,075 and 5,427, respectively) and an 84 percent increase in new enrollees aged 71 and over (2,383 and 4,385, respectively). Because older persons have much higher death rates, this shift in the age distribution will tend to lower the aggregate survival rate. Therefore, the overall survival rate was age adjusted to the age distribution of all new enrollees over all 5 years. This age adjustment tends to mitigate the difference over years. Age-adjusted survival varies from a high of 82 percent in 1981 and 1982 to a low of 80 percent in 1983 and 1984.

Table 19. Dialysis Patient Survival by Year of Renal Failure and by Age, Sex, Race, and Primary Diagnosis

CHAR	1980 (N)	1980 SURV	1980 S.E.	1981 (N)	1981 SURV	1981 S.E.	1982 (N)	1982 SURV	1982 S.E.	1983 (N)	1983 SURV	1983 S.E.	1984 (N)	1984 SURV	1984 S.E.
TOTAL	17,374	82%	0.3%	17,562	82%	0.3%	19,221	81%	0.3%	21,360	78%	0.3%	22,240	79%	0.3%
AGE ADJ TOTAL		81%			82%			82%			80%			80%	
MALE	9,681	82%	0.4%	9,726	83%	0.4%	10,551	81%	0.4%	11,653	78%	0.4%	12,252	78%	0.4%
FEMALE	7,693	82%	0.5%	7,836	82%	0.5%	8,670	82%	0.4%	9,707	78%	0.4%	9,988	79%	0.4%
WHITE	12,056	80%	0.4%	12,334	81%	0.4%	13,281	80%	0.4%	14,347	76%	0.4%	14,952	76%	0.4%
BLACK	4,689	86%	0.5%	4,586	86%	0.5%	5,184	85%	0.5%	6,097	83%	0.5%	6,303	85%	0.5%
OTHER	629	83%	1.6%	642	84%	1.5%	756	84%	1.4%	916	81%	1.3%	985	82%	1.3%
0-10	154	87%	3.3%	157	95%	2.2%	194	90%	2.7%	178	94%	2.3%	207	89%	2.6%
11-20	628	96%	0.9%	587	96%	0.9%	628	96%	1.0%	603	96%	0.9%	581	97%	0.9%
21-30	1,566	92%	0.7%	1,524	94%	0.7%	1,710	93%	0.7%	1,662	93%	0.7%	1,777	92%	0.7%
31-40	2,193	90%	0.7%	2,213	90%	0.7%	2,469	89%	0.7%	2,503	90%	0.7%	2,642	88%	0.7%
41-50	2,461	88%	0.7%	2,494	88%	0.7%	2,533	87%	0.7%	2,823	88%	0.7%	2,913	88%	0.6%
51-60	3,914	84%	0.6%	3,874	84%	0.6%	4,132	84%	0.6%	4,105	82%	0.6%	4,308	83%	0.6%
61-70	4,075	76%	0.7%	4,268	78%	0.6%	4,585	78%	0.6%	5,224	74%	0.6%	4,427	73%	0.6%
71+	2,383	66%	10.0%	2,445	66%	10.0%	2,970	66%	0.9%	4,262	61%	0.8%	4,385	64%	0.7%
DIABETES	2,244	77%	0.9%	3,296	76%	0.8%	4,362	74%	0.7%	4,955	73%	0.7%	5,611	73%	0.6%
GLOMER	2,166	91%	0.6%	3,129	89%	0.6%	4,518	87%	0.5%	4,873	85%	0.5%	4,917	86%	0.5%
HYPERTENSION	2,290	83%	0.8%	3,429	82%	0.7%	4,533	80%	0.6%	4,813	77%	0.6%	5,205	78%	0.6%
OTHER	10,674	81%	0.4%	7,708	83%	0.5%	5,808	83%	0.5%	6,719	77%	0.5%	6,507	79%	0.5%

Because the changes in survival rates seemed to occur primarily between 1982 and 1983, the average 1-year survival rate for the period 1980 to 1982 was compared with the 1983-to-1984 period to try to determine some of the reasons for the downward shift in survival. Table 20 presents the survival rates by age group for these two periods.

Table 20. Dialysis Patient Survival by Year of Renal Failure and Age

Age Group	80-82	83-84	DIFF
0 to 10	90.4%	91.5%	1.1%
11 to 20	96.1%	96.5%	0.4%
21 to 30	93.2%	92.5%	-0.7%
31 to 40	89.6%	89.2%	-0.4%
41 to 50	87.6%	88.0%	0.4%
51 to 60	84.1%	82.4%	-1.7%
61 to 70	77.3%	73.5%	-3.8%
71 and over	65.9%	62.3%	-3.6%
All Persons	81.8%	78.3%	-3.5%

Source: ESRD Medical Information System, HCFA

As can be seen, the trend in survival was not consistent across age groups. Survival rates increased for three age groups (persons aged 0 to 10, 11 to 20, and 41 to 50), while declining for the other five age groups. Of particular interest was the magnitude of change across age groups. Up through age 60, the changes were not great--less than 2 percent. However, for persons aged 61 to 70, there was a decline in survival of 3.8 percent (77.3 percent to 73.5 percent). For persons aged 71 and over, the decline was 3.6 percent (65.9 percent to 62.3 percent).

The question arises as to why there should be a decline in survival in these age groups. One possibility is that the persons treated in 1984 were relatively less healthy than those treated in 1980. There was a 28 percent overall increase in the number of persons (17,374 and 22,240) from 1980 to 1984. If dialysis treatment was extended to persons in 1983 and 1984 who were considered too sick to treat in previous years, the effect would be to increase the case-mix severity of the population, even within age groups. The age group 71 and over is particularly noteworthy. Almost twice as many persons in this age group were treated in 1984 as in 1980.

Diabetes is another factor related to survival risk and is the primary cause of renal failure. As Table 19 shows, persons whose cause of renal failure is diabetes have much lower 1-year survival rates than persons with other causes of renal failure. Also, diabetes has been increasing as a percent of all cases, from 13 percent in 1980 to 25 percent in 1984. However, most of this increase had occurred before 1983.

The Cox Proportional Hazards Model

A multivariate approach was used to control for the various risk factors and their changing proportions by year. A Cox proportional hazards model was used to estimate relative survival across risk groups. The Cox model allows one to estimate the effect of a variable on survival while simultaneously controlling for the effects of other risk factors. The independent variables entered in the model were age, sex, race, primary cause of renal failure, and year of renal failure onset. The last variable was entered to determine if there were year-to-year variations in survival which were independent of the other risk factors.

Table 21 presents the results of the Cox analysis. It shows the relative risk of mortality by prognostic factor and the associated level of significance based on a chi-square distribution.

Table 21
Dialysis Patient Survival (1-Year Survival)
Cox Proportional Hazards Model

Prognostic Factor	Relative Risk	p value
Sex (male vs female)	1.09	.006
White (yes vs no)	1.22	.018
Black (yes vs no)	.90	.221
Age (per 10-year increment)	1.44	.001
Diabetes (yes vs no)	1.52	.001
Hypertension (yes vs no)	.91	.031
Glomerulonephritis (yes vs no)	.69	.001
1981	.98	.693
1982	1.00	.971
1983	1.18	.001
1984	1.06	.286

Source: ESRD Medical Information System, HCFA

Relative risk is a measure of the mortality risk of a given prognostic factor after controlling for other independent variables. For instance, the relative mortality risk of males to females is 1.09. This means that, all things

being equal, males have a 9 percent greater mortality rate than females. Based on a mortality rate for females of about 18.0 percent, males would have a mortality rate of about 19.6 percent.

Because chi-square values are directly proportional to sample size, it becomes increasingly easy to achieve statistical significance with very large samples. This analysis was based on a 20 percent sample of the new ESRD enrollees during 1980 through 1984 (n = 19,950). With such a large sample, this analysis provides a relatively liberal estimate of the statistical significance of prognostic factors.

Table 21 shows that diabetes is the most important factor in mortality, with a relative risk of 1.52 compared to all others. Age is also a very important risk factor, with a relative risk of 1.44 for each additional 10 years of age.

The table also shows the relative risk associated with each year as compared to the base year of 1980. Relative risks in 1981 and 1982 are 0.98 and 1.00, respectively. This indicates that, after controlling for other prognostic factors, the relative mortality in these years was about the same as in 1980. However, in 1983, the relative risk is 1.18, which is significant at the .001 probability level. This shows that after controlling for other prognostic factors, mortality was 18 percent greater for persons whose renal failure occurred in 1983 than for those whose renal failure occurred in 1980. In 1984, the relative risk drops to 1.06 and the p value increases to 0.286, indicating a higher, but not significant, risk associated with renal failure occurring in 1984 as compared to 1980.

The Cox model analysis thus supports the life-table analyses shown in Tables 19 and 20. It appears that there was an increase in mortality among new ESRD patients treated with dialysis that occurred in 1983. Mortality improved in 1984 but did not reach the levels of the 1980-82 period.

Conclusion

Ascertaining the reasons for the decline in survival rates in 1983 is an extremely complex task. A number of changes occurred in the ESRD program that operated simultaneously. Those include (1) an increasing incidence rate (rate of new persons on dialysis), (2) an apparent increase in severity as measured by age distribution and percent of persons with diabetes, (3) an increasing percentage of patients on CAPD, (4) increasing rates of kidney transplantation, (5) the increasing practice of reusing dialysis filter elements, (6) introduction of the composite rate reimbursement in 1983, and (7) introduction of the Medicare prospective payment system for reimbursing inpatient hospital services.

Items (1) and (2) are changes in patient case mix. The analysis presented above attempted to control for these severity changes. However, it is certainly possible that some changes in severity are unmeasured and are working to increase mortality levels. Substantial clinical information would be needed to control adequately for severity levels other than primary diagnosis.

Items (3), (4), and (5) are changes that have been taking place in practice patterns. CAPD is the fastest growing type of dialysis therapy. There is no evidence that CAPD has been associated with higher mortality rates. However, CAPD patients could not be distinguished from hemodialysis patients in this analysis.

Kidney transplantation rates could affect dialysis mortality if the recipients of kidney transplantation were healthier than other dialysis patients. The effect of transplantation would then be to increase patient severity among dialysis patients by removing more of the healthier patients. Although there was a substantial increase in transplantation in 1983 (about 14 percent), it is probably not related to changing dialysis survival. First, there is no evidence that recipients of transplants are healthier than other renal failure patients. Second, the life-table method used in this analysis includes the survival experience of transplant patients for the period prior to transplantation. Third, the biggest increase in mortality occurred among persons aged 65 and over, a group that has very low transplant rates.

The increasing practice of reuse of dialysis filters has been occurring for a number of years. Each year, the Centers for Disease Control, with the cooperation of HCFA, conducts a surveillance of dialyzer reuse and its effect on rates of hepatitis. To date, no relationship has been found.

Items (6) and (7) are reimbursement systems which HCFA implemented in 1983. The composite rate for dialysis was implemented in August of 1983. The prospective payment system was begun in October 1983 and will be phased in over 3 years.

Of the two, the composite rate is likely to have the greatest impact. First, it was implemented earlier in the year and went into effect for all facilities simultaneously.

Second, it relates to care that dialysis patients receive each week, whereas prospective payment is only related to inpatient hospital care. Finally, the composite rate was an actual reduction in payment amounts to dialysis facilities, whereas prospective payment did not reduce payment levels.

The improvement in mortality in 1984 makes it seem less likely that composite rates were responsible for the 1983 mortality increases. If the composite rate was inadequate to maintain quality of care in dialysis facilities, then the effect should have continued into 1984, or even increased because of inflation.

Because the composite rate was introduced in August 1983, it was decided to examine the 1983 patient survival both before and after the beginning of the composite rate. The analysis showed that the rate of increase in mortality in 1983 was as great before as it was after the composite rate went into effect. Thus, it appears that there was a trend of increasing mortality throughout 1983 which was not affected by the composite rate itself.

The extent to which any, or all, of the above factors contributed to increased mortality cannot be determined in this analysis. However, the increasing age of the patient population and the fact that mortality changes are greatest in age groups where growth is largest are suggestive of a change in patient case mix to a more severely ill population at risk.

In addition, the analysis does show a slight improvement in survival in 1984. It is possible that 1983 represented an anomaly in the ESRD mortality rates and that 1984 represented a return to previous rates. Further years of data will be necessary to determine whether the change in 1983 represents a temporary phenomenon or a permanent change.

MEDICARE INPATIENT HOSPITAL USE, BY AGE INTERVAL

In 1984, 98,962 Medicare ESRD beneficiaries were eligible for benefits for at least part of the year. (Note: The dialysis population noted elsewhere in this report is the number of people on dialysis on the date of the survey. The data in this section represent all eligible for any period during the calendar year--hence a larger number.)

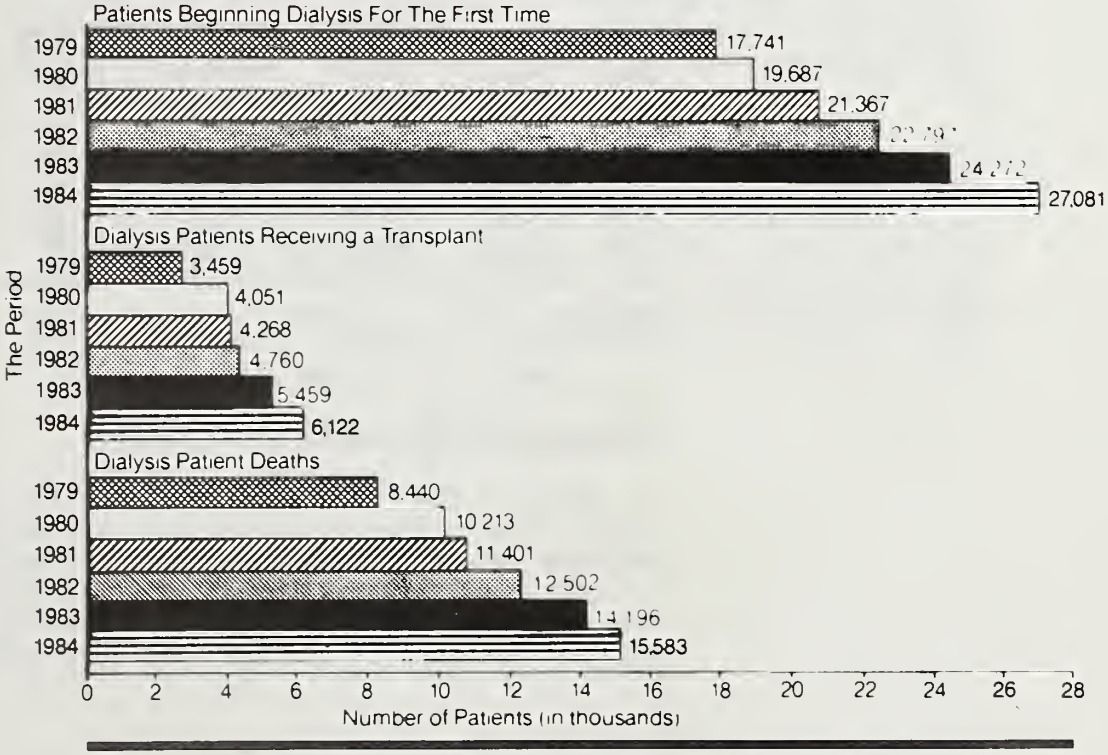
For purposes of this analysis, these persons were divided into the following mutually exclusive and exhaustive categories:

Group	Number of Persons	Percent of Total
(1) Persons on dialysis for the entire eligible year	78,769	79.6%
(2) Persons receiving a transplant in 1984	5,820	5.9%
(3) Persons receiving a transplant in a year prior to 1984, with a functioning graft throughout 1984	13,494	13.6%
(4) Persons receiving a transplant in a year prior to 1984, with a kidney graft failure in 1984	878	0.9%
Total	98,962	100.0%

The analysis that follows considers inpatient utilization separately for each of these patient groups. Figure 17 depicts major reasons for changes in the number of patients treated by suppliers of ESRD services.

Figure 17

Major Reasons for Changes in the Number of Patients Treated by Medicare Certified Suppliers of ESRD Services 1979-1984



SOURCE: ESRD Medical Information System 1979, 1980, 1981, 1982, 1983 and 1984 Facility Surveys

PERSONS ON DIALYSIS FOR THE ENTIRE ELIGIBLE YEAR

In 1984, the patient population on dialysis for the entire year numbered 78,769 and comprised 79.6 percent of all ESRD Medicare beneficiaries. Table 22 shows the distribution of these patients by age with the number of inpatient days and discharges associated with each group. This group is older than the total ESRD beneficiary population: 55 percent are aged 55 years or older. This dialysis population was hospitalized 97,676 times and accounted for 864,034 days of inpatient care. This utilization resulted in a discharge rate per 1,000 beneficiaries of 1,240, a days-of-care rate per 1,000 beneficiaries of 10,969, and an average length of stay per discharge of 8.8 days.

With the exception of the youngest age group (0 to 14 years), there was a direct relationship between age and inpatient use. Compared to persons aged 15 to 24, persons aged 65 and over were hospitalized 40 percent more often (1,010 discharges per 1,000 and 1,410 discharges per 1,000, respectively) and spent 86 percent more days as an inpatient (7,365 days per 1,000 and 13,721 per 1,000, respectively).

Table 22
Discharge Rates, Days-of-Care Rates, and Average Length of Stay for ESRD Beneficiaries, 1984 (Dialysis Patients)

Age Group	Number of Persons	Number of Inpatient Days	Number of Inpatient Discharges	Discharges per 1,000 Persons	Days per 1,000 Persons	Average Length of Stay
0-14	628	5,759	679	1,081	9,170	8.5
15-24	2,897	21,335	2,925	1,010	7,365	7.3
25-34	7,979	66,119	8,470	1,062	8,287	7.8
35-44	10,536	96,019	11,784	1,118	9,113	8.1
45-54	13,628	129,137	15,572	1,143	9,476	8.3
55-64	20,125	230,421	25,860	1,285	11,449	8.9
65+	22,976	315,244	32,386	1,410	13,721	9.7
ALL PERSONS	78,769	864,034	97,676	1,240	10,969	8.8

Source: ESRD Medical Information System, HCFA

PERSONS RECEIVING TRANSPLANTS IN 1984

In 1984, 6,933 Medicare beneficiaries received kidney transplants. They accounted for 5.9 percent of all ESRD Medicare beneficiaries. The utilization of inpatient care by this population is shown in Table 23. In contrast to the dialysis population, the transplant population is much younger, with only 9 percent aged 55 years or older. Due

to the transplant stay itself and associated inpatient stays both before and after the transplant stay, this population experiences high hospitalization rates. The 5,820 persons in this group had 13,531 hospitalizations and were hospitalized for a total of 181,477 days. This resulted in a discharge rate of 2,325 discharges per 1,000 beneficiaries and a days-of-care rate of 31,182 days per 1,000 beneficiaries.

The lowest discharge and days-of-care rates were experienced by the youngest age group, persons 0 to 14. For the remaining persons there was not much difference in utilization by age group. There was only an 8 percent difference in days of care per 1,000 between persons aged 15 to 24 and persons aged 55 to 64 (30,094 and 32,361, respectively).

PERSONS RECEIVING A TRANSPLANT IN A YEAR PRIOR TO 1984, WITH A FUNCTIONING GRAFT THROUGHOUT 1984

This group represents successful transplants from previous years. The 13,494 persons in this group accounted for 13.6 percent of all ESRD Medicare beneficiaries in 1984. Table 24 presents their inpatient utilization for their age distribution, which is similar to that of persons receiving transplants in 1984. Fifty-six percent of this group are between the ages of 25 and 44. Their utilization of inpatient care is much less than for either dialysis or transplant patients. This group was hospitalized 8,337 times for a total of 73,580 days. This amounts to a discharge rate of 618 per 1,000 beneficiaries and a days-of-care rate of 5,453 per 1,000 beneficiaries.

With the exception of the youngest and oldest age groups, in which there were few patients, there was a direct relationship between inpatient use and age. Persons aged 55 to 64 were hospitalized 38 percent more often than persons aged 15 to 24 (689 discharges per 1,000 and 500 discharges per 1,000, respectively) and experienced 88 percent more inpatient days (7,265 days per 1,000 and 3,874 days per 1,000, respectively).

Table 23
Discharge Rates, Days-of-Care Rates, and Average Length of Stay
for ESRD Beneficiaries, 1984 (Transplant Patients)

Age Group	Number of Persons	Number of Inpatient Days	Number of Inpatient Discharges	Discharges per 1,000 Persons	Days per 1,000 Persons	Average Length of Stay
0-14	318	8,700	712	2,239	27,358	12.2
15-24	816	24,557	1,887	2,313	30,094	13.0
25-34	1,603	50,787	3,847	2,400	31,682	13.2
35-44	1,487	46,853	3,484	2,343	31,508	13.4
45-54	1,070	33,458	2,411	2,253	31,269	13.9
55-64	490	15,957	1,108	2,261	32,565	14.4
65+	36	1,165	82	2,278	32,361	14.2
ALL PERSONS	5,820	181,477	13,531	2,325	31,182	13.4

Source: ESRD Medical Information System, HCFA

Table 24
Discharge Rates, Days-of-Care Rates, and Average Length of Stay
for ESRD Beneficiaries, 1984
(Functioning-Graft Patients)

Age Group	Number of Persons	Number of Inpatient Days	Number of Inpatient Discharges	Discharges per 1,000 Persons	Days per 1,000 Persons	Average Length of Stay
0-14	459	2,143	276	601	4,669	7.8
15-24	1,905	7,380	952	500	3,874	7.8
25-34	4,062	20,215	2,374	584	4,977	8.5
35-44	3,516	20,607	2,280	648	5,861	9.0
45-54	2,390	14,931	1,655	692	6,247	9.0
55-64	1,066	7,745	734	689	7,265	10.6
65+	96	599	66	688	5,823	8.5
ALL PERSONS	13,494	73,580	8,337	618	5,453	8.8

Source: ESRD Medical Information System, HCFA

PERSONS RECEIVING A TRANSPLANT IN A YEAR PRIOR TO 1984, WITH A KIDNEY GRAFT FAILURE IN 1984

This group of ESRD beneficiaries is made up of those persons who received a kidney transplant before 1984 and experienced a graft failure in 1984. There were 878 such persons, representing 0.9 percent of the total ESRD Medicare beneficiary population. Table 25 presents the inpatient utilization rates for these persons. The table shows that the rejection of a transplant is associated with a high rate of hospitalization. These persons accounted for 2,413 hospitalizations and a total of 23,075 inpatient days. This amounts to a discharge rate of 2,748 discharges per 1,000 beneficiaries and a days-of-care rate of 26,281 per 1,000 beneficiaries.

There is a slight direct relationship between age and utilization in this patient population, with persons aged 45 to 54 experiencing 24 percent more inpatient days than persons aged 15 to 24.

Table 25
Discharge Rates, Days-of-Care Rates,
and Average Length of Stay
for ESRD Beneficiaries, 1984
(Graft-Failure Patients)

Age Group	Number of Persons	Number of Inpatient Days	Number of Inpatient Discharges	Discharges per 1,000 Persons	Days per 1,000 Persons	Average Length of Stay
0-14	39	899	95	2,436	23,051	9.5
15-24	139	3,356	356	2,561	24,144	9.4
25-34	242	6,047	683	2,822	24,988	8.9
35-44	240	6,718	697	2,904	27,992	9.6
45-54	146	4,357	409	2,801	29,842	10.7
55-64	64	1,410	147	2,297	22,031	9.6
65+	8	288	26	3,250	36,000	11.1
ALL PERSONS	878	23,075	2,413	2,748	26,281	9.6

Source: ESRD Medical Information System, HCFA

COST SAVINGS AND OTHER ESRD EXPERIMENTS

HCFA's Office of Research and Demonstrations is funding several studies related to the ESRD program. They address many of the basic policy, program evaluation, and cost-containment issues involved in administering the program.

Listed below are the research and demonstration studies described in the following pages:

- o National Kidney Dialysis and Kidney Transplantation Study.
- o Assessment of Competitive Health Insurance Proposals in the End-Stage Renal Disease Program.
- o Developing Incentive Systems To Increase the Supply of Cadaveric Kidneys for Transplants.
- o Relative Effectiveness and Cost of Transplantation and Dialysis in End-Stage Renal Disease.
- o Organ Donor Education Project.
- o Costs, Outcomes, and Competition in the End-Stage Renal Disease Program.
- o End-Stage Renal Disease Nutritional Therapy Study.
- o Severity of Illness in the End-Stage Renal Disease Population in Northern Florida.
- o Comparison of Quality of Life of End-Stage Renal Disease Patients.
- o Waiver for the Northwest Kidney Center, Seattle, To Be Reimbursed Directly for Providing Home Dialysis Training Services.
- o Comparative Analysis of the Cost and Outcomes of Kidney Transplants.

NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANT STUDY

The purpose of this study is to analyze the impact of alternative types of therapy on ESRD patients. Patient outcomes are measured in terms of the patient's quality of care. Survey instruments included direct patient interviews; facility-based medical records abstracts; completion of patients' medical-expense diaries; and HCFA program data from entitlement forms, provider certification records, facility survey files, facility cost reports, facility and provider reimbursement records, and other medical information files.

In general, the study found that patients are not randomly assigned to different treatment modalities and that case-mix differences do affect patient outcomes. There were significant differences in the measures of quality of care and quality of life by type of therapy, and these

differences persisted after adjusting for differences in patient case mix. Also, significant declines in labor force participation were associated with the onset of renal disease.

In the study, only about one-half of the patients use rehabilitation services, and their use of services varied significantly across types of treatment modalities. Both short- and long-term complications were associated with organ transplantation. Serious complications were more likely to be present among ESRD patients who had experienced a failed transplant than among patients who had successfully functioning allografts. These differences, however, were not attributable to patient case-mix differences, because the two patient transplant groups did not differ with regard to age, sex, race, education, and primary disease diagnosis.

The final project report is being published under the Health Care Financing Special Report series. It is expected to be available in the spring of 1986.

ASSESSMENT OF COMPETITIVE HEALTH INSURANCE PROPOSALS IN THE END-STAGE RENAL DISEASE PROGRAM

Competitive Approaches to Reimbursement

Throughout 1984, the Urban Institute, under a cooperative agreement they were awarded in March 1983, produced reports on the feasibility of various competitive approaches to reimbursing ESRD services: competitive bidding; partial capitation covering only outpatient services; global capitation covering essentially all medical care costs; and voucher systems that allow patients to share in the savings of cost-reducing shifts of services.

ESRD Capitation

On December 31, 1984, the El Camino Hospital Corporation was awarded a 5-year cooperative agreement to develop and test a program under which capitation payments will cover all Medicare benefits to ESRD patients, including transplants.

During the first 2 years, El Camino, using Urban Institute as a subcontractor, will collect and analyze data to develop a rate-setting methodology. The negotiated capitation rate will be approximately 95 percent of the actuarially projected ESRD capitation rate for California.

After HCFA approves the capitation rate and the Medicare waivers, a disease management organization (DMO) will be formed to operate like an IPA-HMO, with provider groups, hospitals, and dialysis centers sharing part of the risk.

The DMO will begin operating in Santa Clara County and will expand in planned phases in the San Francisco metropolitan area, with the goal of enrolling 1,000 patient-members by the end of the fifth project year.

DEVELOPING INCENTIVE SYSTEMS TO INCREASE THE SUPPLY OF CADAVERIC KIDNEYS FOR TRANSPLANTS

This study is being conducted under a cooperative agreement with Brandeis University. Using survey methodologies, this project will evaluate alternative approaches to increasing the participation of nongovernmental actors in organ procurement programs. The end result of the research will be a set of HCFA policy recommendations designed to improve the effectiveness of organ procurement networks and so increase the number of kidneys available for transplantation.

The cooperative agreement was initiated in June 1983. The methodology entails surveys of major participants in the organ procurement process. These include hospital administrators, directors of nursing, intensive care unit nurses, and neurosurgeons. Each group of these professionals was administered a questionnaire designed to elicit information concerning their knowledge and personal opinions about organ procurement, perceived barriers to organ procurement, and potential recommendations for improving the organ procurement process. In addition, donor families and the general public were interviewed to collect information on public attitudes toward organ procurement.

Data collection has been completed and the project is in the analysis phase. Much of the effort in 1984 in this cooperative agreement was in support of the National Task Force on Organ Transplantation and the Federal Office of Organ Transplantation.

RELATIVE EFFECTIVENESS AND COST OF TRANSPLANTATION AND DIALYSIS IN END-STAGE RENAL DISEASE

This study is being conducted under a cooperative agreement with the University of Michigan. It is intended to perform a comprehensive assessment of the cost effectiveness of ESRD treatment under different treatment modalities, an assessment of the impact of cyclosporine on transplant success, and a life-table analysis of risk factors for patient and graft survival. The study will use data from the Michigan Kidney Registry, supplemented by survey information and medical record abstracts. Because of the design of the study, it is anticipated that the project will demonstrate the utility of a longitudinal, patient-specific data system for policy decisionmaking at the Federal level.

Activities in the three main research areas--quality of life, survival, and costs--have generally proceeded as planned in the second year. Most of the 500 patient interviews for the quality-of-life component have been completed for the first cohort of patients (November 1, 1981-October 31, 1983). Univariate and multivariate survival analyses have been performed on the full universe of 1,842 patients in the first cohort. Development of the cost analysis component has lagged somewhat because of problems in obtaining the historical reimbursement files.

Progress also continues in secondary goals of the research project, such as identification of diabetic etiological factors in end-stage renal disease, use of the Michigan Kidney Registry data for a variety of research purposes (for example, studies in geriatric nephrology), and study of the relationship between immunosuppressive agents and malignant tumors.

ORGAN DONOR EDUCATION PROJECT

The Oregon Organ Donor Program, under a grant awarded in May 1983, has been testing public education methods for increasing the number of drivers licenses coded for organ donation. The Oregon Department of Motor Vehicles (DMV) used videotapes: a 2-minute public education tape, and an 8-minute tape shown to DMV personnel to train them in promoting organ donation. In addition, an information manual about organ donation procedures was developed and distributed to medical personnel, chaplains, and others who influence potential donors and their next of kin.

Preliminary evaluation has demonstrated that the video tapes have the potential for significantly increasing donor designation rates, but the effectiveness of the tapes is dependent upon the commitment of DMV staff to the program. A final report will be submitted to HCFA in the summer of 1986.

COSTS, OUTCOMES, AND COMPETITION IN THE END-STAGE RENAL DISEASE PROGRAM

This project began in June 1981 under a cooperative agreement with the Urban Institute. The purpose of the project was to aid in the overall assessment of the ESRD program by studying three aspects:

- The determinants of the total cost of the program.
- Some measures of the health outcomes produced by the program.
- Alternative ways of organizing and improving services.

Particular attention was given to the effects of competition on the cost and quality of care among facilities in an area.

Six major papers have been produced during the grant period:

- "Pro-Competitive Health Insurance Proposals and Their Implications for the ESRD Program";
- "Competition and Efficiency in the ESRD Program";
- "Financial Incentives and Policy Goals of the End-Stage Renal Disease Program";
- "Charges to Victims: An Evaluation of Reimbursement Policies in the United States ESRD Program";
- "CAPD: On the Debate Over Efficiency and Cost--Some Preliminary Evidence"; and
- "Survival Analysis of Dialysis Patients."

In December 1984, a report of recommendations for revising ESRD system files was received. The final report is expected by late 1986.

END-STAGE RENAL DISEASE NUTRITIONAL THERAPY STUDY

In accordance with the congressional mandate in Public Law 96-499, the Modification of Diet in Renal Disease study will seek to determine the potential for nutritional therapy to delay or interrupt the progression of renal disease and to delay or obviate the need for dialysis.

The study will be conducted jointly by the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases and HCFA. The study began in September 1984, with a 1-year developmental phase. Six clinical sites in five states (California, Iowa, Maryland, Massachusetts, and Tennessee) and a central laboratory and data center in Ohio have been selected to participate. The principal investigators from these sites are meeting as a steering committee to develop a clinical protocol and operations manual during the developmental phase of the study.

The second phase of the study will be a 2-year pilot project involving approximately 108 patients at the six clinical sites. Information from this phase will be used in the design of the third phase, a 3- to 5-year study involving approximately 600 patients. The fourth phase will be a 1-year evaluation of the safety, efficacy, and cost-effectiveness of nutritional therapy.

SEVERITY OF ILLNESS IN THE END-STAGE RENAL DISEASE POPULATION IN NORTHERN FLORIDA

The purpose of this study, which is being conducted under a cooperative agreement with the University of Florida, is to develop and test measures of severity of illness that predict resource-consumption levels in the ESRD program. These measures will be based on the acute physiology and chronic health evaluation (APACHE) system, which was developed to measure therapeutic effort and resource costs in intensive care units. Two components of APACHE, the therapeutic intervention scoring system (TISS) and the acute physiology score (APS), will be adapted to the special characteristics of the ESRD patient receiving dialysis. The TISS and APS will then be used to measure ESRD case mix and resource consumption.

The major activity of the first year of this study involved the development of an instrument to measure variations in the severity of illness in the chronic hemodialysis population. The instrument includes physiologic measures, dialysis treatment variations, and measures of comorbidities, as well as socioeconomic and behavioral factors.

Seven hemodialysis units have agreed to participate in the study. The number of patients to be included will be approximately 560. A final report is scheduled for the spring of 1987.

COMPARISON OF QUALITY OF LIFE OF END-STAGE RENAL DISEASE PATIENTS

This study is being conducted under a cooperative agreement with the University of Minnesota. The objective of the study is to evaluate the quality of life of patients on different therapeutic regimens for end-stage renal disease. The following groups will be compared:

- Transplant recipients randomly allocated to conventional immunosuppression.
- Transplant recipients randomly allocated to immunosuppression with cyclosporine.
- Patients on hemodialysis.
- Patients on continuous ambulatory peritoneal dialysis.
- A historical control group of patients who received transplants in 1970-73.

Clear-cut differences in survival do not necessarily distinguish among the above treatment modalities. Comparative quality of life is, therefore, an important criterion.

This study is entering its second and final year. Information is available on 83 incenter hemodialysis patients, 510 CAPD patients, and 91 transplant recipients (40 receiving conventional immunosuppressive therapy and 51 receiving cyclosporine).

There are pronounced differences in objective measures of rehabilitation. More than 80 percent of male transplant recipients with functioning grafts work or are in school at least part time (a proportion that is consistent with that seen nationally), but only 30 percent of male incenter hemodialysis patients have achieved an equal level of rehabilitation. Of the male CAPD patients, 46 percent work or attend school at least part time. Patterns among female patients are similar but less pronounced.

Transplant patients also have the best subjective sense of well-being, but the differences are smaller in magnitude. Transplant patients who receive cyclosporine score consistently higher on measures of well-being than those on conventional therapies, in part because of the lower incidence of rejection episodes and of complications of steroid therapy.

WAIVER FOR THE NORTHWEST KIDNEY CENTER, SEATTLE, TO BE REIMBURSED DIRECTLY FOR PROVIDING HOME DIALYSIS TRAINING SERVICES

In November 1984, a 4-year waiver-only cooperative agreement was awarded to the Northwest Kidney Center (NKC) in Seattle, Washington. This agreement will allow NKC to send its own training staff to remote dialysis facilities in the State to train patients for home dialysis and be reimbursed at their own composite rate rather than the composite rate of the site where the training occurs, as well as be reimbursed for travel and accommodation expenses of the training staff.

This regionalization of home training would mean that small, remote dialysis facilities would not have to acquire their own experienced training staff. This project is expected to involve small numbers of patients, precluding statistical evaluation; however, descriptive data will permit some conclusions to be drawn regarding the potential cost effectiveness of regionalized home dialysis training.

COMPARATIVE ANALYSIS OF THE COST AND OUTCOMES OF KIDNEY TRANSPLANTS

This study is being conducted under a cooperative agreement with the Battelle Corporation and is a multicenter observational analysis of the impact of cyclosporine on renal transplantation. A sample of 300 patients contributed by eight major centers experienced in the use of cyclosporine will be studied in depth. Detailed information on outcomes (mortality, complications, disability) and costs will be collected in this sample and analyzed in terms of major prognostic factors. In addition, extensive data of a medical or biologic and of a sociological nature will be obtained. The representativeness of the sample will be validated by comparison with the universe in the HCFA Medical Information System data base.

A collaboration with the scientific studies committee of the American Society of Transplant Surgeons was formalized, and a working group of physicians to advise and guide the biomedical component of the study was impaneled and met twice. The supplementary questionnaires designed to gather medical data were drafted and finalized after review by the medical working group. Patient-selection criteria have been finalized. Participating transplant centers have been selected, and subcontracts for data acquisition have been negotiated. The second year of the project will be devoted largely to data collection.

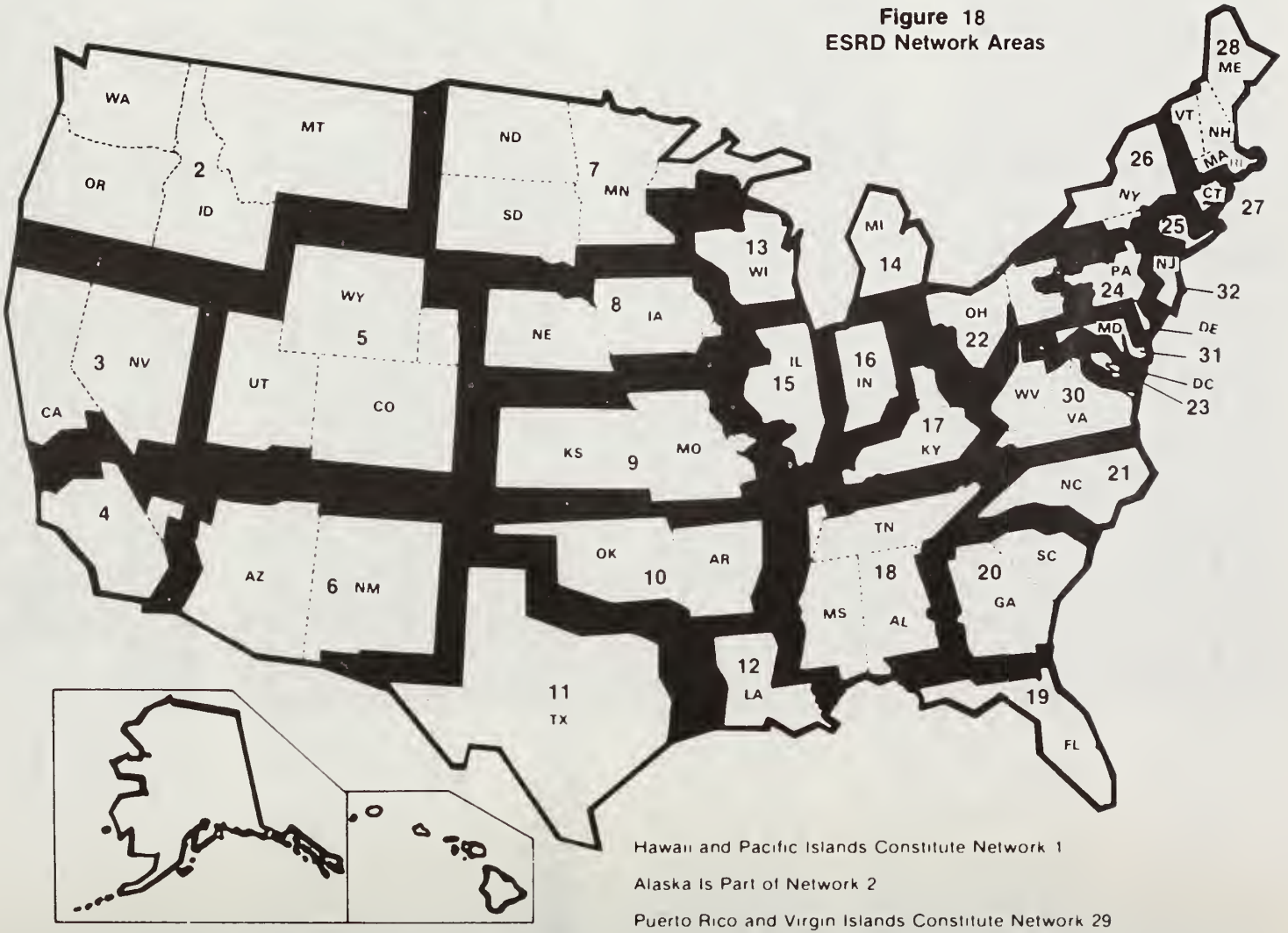
ESRD NETWORK ORGANIZATIONS

Section 1881 of the Social Security Act authorized the establishment of ESRD Network organizations to promote high-quality care and efficient distribution of resources in the delivery of kidney dialysis and transplantation services. There are 32 network organizations composed of representatives from each dialysis and transplant facility, as well as at-large members representing ESRD patients and professional disciplines, such as social workers, nurses, and dietitians who are involved in the delivery of ESRD services. Figure 18 shows ESRD network areas. Total funding for the networks during 1984 was approximately $5 million.

Network efforts during 1984 focused on achieving specific goals in quality assurance (QA), data management, and network administration:

- QA initiatives included conduct of a networkwide QA program, the provision of technical direction to assist individual facilities in designing an internal QA program, continued efforts to increase home dialysis and transplantation, and maintenance of a formal patient grievance mechanism.

Figure 18
ESRD Network Areas



Hawaii and Pacific Islands Constitute Network 1

Alaska Is Part of Network 2

Puerto Rico and Virgin Islands Constitute Network 29

- Data management activities included maintaining data and information to support the networks' QA initiatives and processing information for the HCFA Medical Information System.

- Network administration activities assured organizational and fiscal accountability within the organizations.

CHAPTER VIII. REPORT OF MEDICARE VALIDATION SURVEYS OF HOSPITALS ACCREDITED BY THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS (JCAH)

INTRODUCTION

The purpose of the validation program is to determine the effectiveness of the JCAH accreditation process in providing reasonable assurance that hospitals comply with the intent of the Medicare Conditions of Participation. Each year, a statistical sample of the approximately 5,100 JCAH-accredited hospitals is selected for validation surveys. Under contract with the Secretary, State agencies (SAs) conducted 46 validation surveys during FY 1984.

STATUTORY BACKGROUND

Section 1865 of the Social Security Act provides that JCAH-accredited hospitals are deemed to meet the requirements of the conditions of participation, except for utilization review or other standards the Secretary promulgates that are higher than JCAH standards. Thus, JCAH-accredited hospitals are not subject to annual SA surveys to assess compliance with the conditions of participation. Subsection 1864(c) of the act authorizes the Secretary to enter into an agreement with any State to survey hospitals accredited by JCAH on a selective sample basis or in response to substantial allegations of significant deficiencies that affect the health and safety of patients.

ACCREDITATION PROCESS

The purpose of a JCAH accreditation survey is to assess the extent of a hospital's compliance with JCAH standards. After the completion of the onsite survey, JCAH makes an accreditation decision.

Prior to January 1, 1982, the maximum period of JCAH accreditation was 2 years, which was given to hospitals fully meeting JCAH standards. A hospital found to be in substantial compliance with JCAH standards, although demonstrating certain shortcomings, received a 1-year accreditation.

On January 1, 1982, JCAH discontinued both 1- and 2-year accreditations by changing its accreditation program to a 3-year accreditation with a "contingency" procedure. Under JCAH's new accreditation program, a hospital may receive a 3-year accreditation; a 3-year accreditation with a contingency; or in cases where a hospital fails to achieve substantial overall compliance, no accreditation. A contingency stipulates that the accreditation will be withdrawn if the hospital fails to correct its deficiencies within a specified amount of time.

JCAH, through the use of focused onsite resurveys and/or written reports prepared by the hospital, determines whether the hospital has corrected the deficiencies adequately

to retain accreditation. The contingency accreditation process is analogous to a Medicare resurvey, as they both assess correction of deficiencies. If corrections are not completed as specified in the contingency, the accreditation may be withdrawn. When JCAH increased its accreditation cycle to 3 years, it strengthened existing monitoring mechanisms to include periodic self-survey reports and/or focused onsite surveyor revisits.

VALIDATION AND ALLEGATION PROCESS

The Health Care Financing Administration (HCFA) selects, from scheduled JCAH accreditation surveys, a statistical sample of accredited hospitals for validation surveys. The random selection reflects the urban-rural mix of hospitals and the range of different sizes of hospitals. This permits HCFA to apply its findings to the universe of JCAH hospitals. SAs survey these hospitals using the Medicare Conditions of Participation for Hospitals.

In addition to the sample hospitals, an accredited hospital is subject to an SA survey when there is an allegation that significant deficiencies threaten the health and safety of patients. Allegation surveys evaluate only the specified condition(s), as authorized by HCFA's regional offices. If a significant deficiency is found in the specified condition(s), the investigation is expanded to a full survey.

In both sample and allegation surveys, if significant deficiencies are found, the hospital is placed under SA surveillance until the deficiencies are corrected. The hospital is no longer deemed to meet the Medicare Conditions of Participation, and the SA monitors the correction of any deficiency as if the hospital were unaccredited.

In this report period JCAH performed 1,394 surveys. Twenty-six percent of the hospitals surveyed by JCAH (359 of 1,394) received 3-year accreditations without contingencies, 32 percent (450 of 1,394) received accreditations requiring written contingency reports, 18 percent (257 of 1,394) received accreditations requiring contingency onsite visits, and 22 percent (304 of 1,394) received contingencies requiring both written reports and onsite visits. Two percent (24 of 1,394) were not accredited. Thus, 72 perpercent of all accredited hospitals surveyed by JCAH during 1984 received contingencies (32 percent + 18 percent + 22 percent) as compared to 87 percent of the validated hospitals.

VALIDATION FINDINGS

In FY 84, HCFA's analysis was conducted in two discrete areas: Life Safety Code (LSC) and General Health and Safety requirements.

LIFE SAFETY CODE

The LSC of the National Fire Protection Association is a consensus standard adopted by reference in Federal regulations that provides a reasonable level of safety from fire and other emergencies. During FY 84, 72 percent (33 of 46) of validated hospitals were in compliance with the LSC. (See Table 1.) For all hospitals validated prior to this report period, 48 percent (379 of 785) were in compliance with the LSC.

This improvement can be attributed to Medicare's adoption of the Fire Safety Evaluation System (FSES) for conducting validation surveys and assessing compliance with the LSC. The FSES was developed by the National Bureau of Standards and is a method for assessing compliance with LSC requirements. The FSES permits a facility to employ alternative measures for meeting LSC requirements while providing an equivalent level of fire safety. Since adoption of the FSES there is more similarity between the JCAH and Medicare LSC surveys because both are using FSES.

Medicare recommended in 1980 that JCAH receive additional training in surveying for smoke barriers. These construction requirements are important because the smoke barriers limit the spread of smoke and toxic gases. Inhalation of these gases is the most frequent cause of death in fires. As demonstrated by JCAH citations in smoke-barrier deficiencies, there continues to be improvement in surveying for compliance with this requirement.

The LSC requires that hazardous areas have either a 1-hour fire-resistive separation or sprinkler protection. Severe hazardous areas require both separation and sprinklers. Laboratories, previously the area most often deficient in this requirement, were improved. This year, however, HCFA noted hazardous area deficiencies in soiled-linen rooms and general storage areas.

Both JCAH and Medicare cited a large number of obstructed-corridor and anesthetizing-area humidity-control deficiencies. Obstructed corridors may limit egress in an emergency. Anesthetizing-area humidity control reduces the hazard of infection by diluting and removing airborne microbial contamination and diluting flammable gases. It also contributes to odor control and comfort of personnel.

HCFA suggested surveyor training in identifying hazardous- and anesthetizing-area and obstructed-corridors deficiencies.

Table 1
Validation Surveys

Accredited Hospitals Found in Compliance
by Medicare State Survey Agencies

		All Previous Report Periods		Current Report Period FY 1984	
		No.	%	No.	%
General Health & Safety	In Compliance	720	92	37	80
	Total Surveys	785		46	
Life Safety Code	In Compliance	379	48	33	72
	Total Surveys	785		46	

GENERAL HEALTH AND SAFETY

During this report period, Medicare found 80 percent (37 of 46) of JCAH-accredited hospitals receiving validation surveys in compliance with general health and safety conditions. (See Table 1.) This is consistent with the range of percentages in compliance (83-96 percent) in all previous report periods.

With respect to the general health and safety conditions for validated hospitals, the nursing and laboratory conditions are most frequently found out of compliance. (See Table 2.) These findings are consistent with current and prior report periods for both accredited and unaccredited hospitals.

JCAH accepts accreditation by the College of American Pathologists (CAP), an independent accrediting body, in lieu of its own surveys. JCAH directly surveyed laboratories in 48 percent (22 of 46) of the validated hospital surveys; the balance were surveyed by CAP. JCAH and Medicare differed on their significant findings in 14 percent (3 of 22) of the JCAH-surveyed laboratories. Nine percent of all validated hospitals (4 of 46) were found out of compliance with the laboratory condition. In these hospitals, Medicare surveyors identified significant deficiencies in the quality control standard. In one case, the Medicare surveyor documented that the deficient practices began subsequent to the JCAH survey.

Table 2
Validation Surveys Compared to All
Unaccredited Medicare Surveys
for Nursing and Laboratory Conditions

		Current Report Period FY 1984			
		JCAH Sample		Medicare Surveys	
		No.	%	No.	%
Nursing	In Compliance	43	93	882	93
	Total Surveys	46		945	
Laboratory	In Compliance	42	91	902	95
	Total Surveys	46		945	

Significant differences were noted between Medicare and JCAH survey findings in two hospital laboratories. One laboratory that Medicare found out of compliance demonstrates a different interpretation of the number of quality control materials required in clinical chemistry. (JCAH requires one quality control material per test run and Medicare requires two.) Effective January 1985, JCAH will initiate measures to increase their requirements to be equivalent to those of Medicare (two quality control materials per test run).

SUBSTANTIAL ALLEGATION FINDINGS

For this report period, 167 hospitals received allegation investigations. Sixteen percent (26 of 167) were found out of compliance with one or more conditions. This is consistent with the percentage found out of compliance in the last reporting period (14 percent). Of these hospitals, 4 percent (6 of 167) were found out of compliance with the LSC. Over the previous report period, an average of 11 percent of these hospitals had LSC deficiencies. This decrease parallels the improvement in validation findings.

Eight percent (14 of 167) of these hospitals were out of compliance with nursi g standards, which is also consistent with previous reporting periods. (Last reporting period, 9 percent of allegation-investigation hospitals were out of compliance in nursing.) For all other general health and safety conditions, the number of hospitals out of compliance ranged from 0 percent to 6 percent.

CONCLUSION

Considering both validation surveys and complaint investigations, HCFA found that 20 percent of all hospitals surveyed were placed under SA surveillance. This is consistent with the range in recent years--15 percent for FY 83 and 20 percent for FY 82. This is also consistent with the range for unaccredited hospitals, which were found out of compliance with one or more conditions at the rate of 24 percent. (See Table 3.) This demonstrates equivalency between the JCAH and Medicare survey processes. Except for LSC, laboratory, and nursing conditions, both validation surveys and allegation investigations found all other conditions out of compliance in only 3 percent of hospitals surveyed.

The LSC remains the most difficult requirement for JCAH surveyors to evaluate and for accredited hospitals to meet. There is, however, an improvement from prior years in the number of hospitals meeting the LSC. To continue this trend, HCFA recommends that JCAH surveyors receive training in surveying for obstructed corridors, hazardous areas, and anesthetizing-area humidity-control requirements.

It is through JCAH and HCFA survey efforts that health care facilities continue to improve. The validation program is a check and a health stimulus for both JCAH and SAs. Without the basis for exchange and comparison of results, both programs would suffer. As long as the standards and program management of both agencies continue to develop and improve, the objectives and intent of both will benefit.

The hospital validation program and the JCAH accreditation program are operating successfully. Because it monitors both programs closely, HCFA is alert to any significant changes and takes immediate corrective actions if problems are identified.

Table 3
Validation Surveys Compared to All
Unaccredited Medicare Surveys for Hospitals

		Current Report Period FY 1984			
		JCAH Sample & Allegation		Medicare Surveys	
		No.	%	No.	%
Hospitals in Compliance with all Conditions	In Compliance	170	80	714	76
	Total Surveys	213		945	

CHAPTER IX. MEDIGAP VOLUNTARY CERTIFICATION PROGRAM REPORT (Section 1882(f)(2) of Title XVII)

BACKGROUND

Congressional studies conducted prior to 1980 found many abuses in the sale and marketing of Medicare supplement or "Medigap" health insurance. There were no Federal standards for Medicare supplement coverage and few States had adopted programs specifically to regulate these types of policies. In June of 1980, Congress enacted Public Law 96-265, which added Section 1882 to Title XVIII of the Social Security Act. This law, usually referred to as the Medigap law, initially was staunchly opposed by insurance regulators and the insurance industry. The regulation of the business of insurance has traditionally been the responsibility of the States under the McCarran-Ferguson Act of 1945, and the Medigap law was perceived by some as an encroachment upon States' rights. This perception resulted from a fear that the Federal Government would necessarily become greatly involved in individual insurance department operations in order to enforce the law. This has not proved to be the case, however, and the relationship between the Federal Government and the States has been a cooperative one. State and Federal agencies are working together toward the common goal of providing the best protection available for elderly citizens.

PROVISIONS OF MEDIGAP LAW

The Medigap law established Federal minimum standards based primarily on the provisions contained in the 1979 National Association of Insurance Commissioners (NAIC) Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Act. The law, however, expands upon the model's requirements by extending its jurisdiction to certain group policies and by adding loss-ratio requirements for both group and individual policies. In addition, it provides for the establishment of the Supplemental Health Insurance Panel and a Federal Voluntary Certification Program for Medicare supplement policies, and it includes criminal penalty provisions for certain abusive sales practices.

The law also requires the Secretary to submit to Congress no later than July 1, 1982, and periodically as may be appropriate thereafter (but not less than once every 2 years), a report evaluating the effectiveness of the certification procedure and the criminal penalties established under this section.[1]

---

[1] On March 3, 1987, the Department of Health and Human Services issued a Report to Congress: Study of Health Insurance Designed to Supplement Medicare and Other Limited Benefit Health Insurance Sold to Medicare Beneficiaries. That report, mandated by section 507(f) of Public Law 96-265 studied the comparative effectiveness of various State approaches in the regulation of Medicare supplemental policies. It explored three issues: (1) whether there is a need for a mandatory Federal regulatory

THE VOLUNTARY CERTIFICATION PROGRAM

Under the Voluntary Certification Program, insurers selling Medigap policies not approved by the Supplemental Health Insurance Panel may voluntarily submit such policies to be reviewed by the Secretary of the Department of Health and Human Services (HHS). Those policies found to meet or exceed the Federal minimum standards will be certified, and the insurer will be authorized to display a Federal emblem on the policy. The emblem is authorized for use only in States subject to the Federal program, regardless of whether the same policy is marketed in States not under the program.

PARTICIPATION

The Supplemental Health Insurance Panel determined that the Voluntary Certification Program should be implemented in four States--Massachusetts, New York, Rhode Island, and Wyoming--and three territories: Guam, the Virgin Islands, and American Samoa.

Only two insurers have submitted policies for review under the Voluntary Certification Program, and no policies have been certified to date. Although the deficiencies noted in the policies submitted were seemingly minor, the insurance companies involved have not resubmitted the policies nor indicated that they have made the necessary changes.

The fact that the Voluntary Certification Program applies only to a very few States and jurisdictions in itself limits the program's direct impact. In this same respect, however, the Voluntary Certification Program was responsible for the overwhelming success of the Medigap law, since it served as an incentive for such a large number of States to adopt their own programs regulating Medigap policies. Indeed, the number of States adopting the 1979 NAIC Model is the largest ever to adopt any NAIC model.

In addition to the small number of States involved, there are other possible reasons for such a limited reaction to the program. Foremost is the perception on the part of State insurance regulators and the insurance industry that such a program is an infringement upon the individual State's right to regulate the business of insurance.

---

program; (2) whether there is a need for standards for health insurance policies other than Medicare supplements sold to Medicare beneficiaries; and (3) whether there are other appropriate means that would enhance effective State regulation of Medicare supplemental policies. The report concluded that there is no need for a mandatory Federal program and recommended States should be encouraged to adopt appropriate minimum benefit standards for private health insurance sold to Medicare beneficiaries and to adopt several actions to enhance effective State regulation of Medicare supplemental policies.

As noted earlier, the Federal-State relationship resulting from the Medigap law has proved an amiable one, but there is still much apprehension in the insurance community about a "Federal" emblem being placed on a private insurance policy. It is felt that the emblem may encourage the practice of "twisting," whereby insurance agents replace existing coverage with new coverage that offers no greater benefits or even lower overall benefit levels. Some insurers also feel that the emblem may confuse some elderly Medicare beneficiaries, since it may appear only on those policies sold in States subject to the Voluntary Certification Program.

Most insurers design their Medigap policies to be marketed in a number of States. So a situation would exist where a policy would be able to display the emblem in a State under the Federal program, but the exact same policy could not bear the emblem in a State that was not under the program. The additional cost involved in preparing policies for distribution in just a few States also is a deterrent to seeking certification.

IMPACT

Since the Secretary has not yet certified any policies under the Voluntary Certification Program, there is no data available to show the direct impact of the certification procedure on market share, value, and cost to individuals entitled to benefits under Title XVIII. As stated earlier, however, the indirect impact of the program has been its very positive effect of prompting States to implement their own approved regulatory programs for Medicare supplement policies. Without the incentive provided by the Voluntary Certification Program, it is doubtful that as many States would have changed their existing programs. Also, the Supplemental Health Insurance Panel is now responsible for monitoring the continued compliance of the approved States, and the Voluntary Certification Program should act as a deterrent to those States considering changes to their regulatory programs that would adversely affect their continued compliance with the Medigap law.

The Medigap law also established Federal criminal penalties for certain fraudulent or abusive marketing practices. Section 1882(d) provides criminal sanctions for furnishing false or misleading information for the purpose of obtaining certification; for misrepresentation as an agent of the Federal Government for the purpose of selling insurance to supplement Medicare; for knowingly selling insurance which substantially duplicates benefits of another policy held by the purchaser; and for knowingly advertising, soliciting, or offering for sale mail order policies in a State without the approval of the State insurance commissioner. Anyone

convicted of violations of Section 1882 is subject to a fine of up to $25,000 and/or imprisonment for up to 5 years.

IMPLEMENTATION

The Health Care Financing Administration (HCFA), given the responsibility for implementing the penalty provisions of the Medigap law, continues to investigate possible violations of Section 1882(d). HCFA has developed a system of coordination for reporting these violations that includes the 10 HCFA regional offices, the Social Security Administration (SSA), the Office of the Inspector General (OIG) for the Department of Health and Human Services, and the Department of Justice (DOJ).

The initial screening of complaints is generally done through HCFA's regional offices. These offices are also responsible for furnishing information to State insurance departments about specific complaints. The OIG investigates complaints that have been referred to them by HCFA and coordinates this activity with State insurance departments. OIG also serves as the liaison between State insurance departments and the U.S. Attorneys, who have been contacted by the Fraud Division of DOJ regarding the Medigap law and encouraged to prosecute violations of this section.

HCFA also receives many complaints about practices which, while not in violation of the Medigap law, are possible violations of other Federal statutes. These most often involve misleading advertising and mail order solicitations for Medicare supplement insurance. HCFA's efforts in this area are being coordinated with other Federal agencies such as the Federal Trade Commission and the Postal Inspection Service.

ACTIVITY IN FY 84

During FY 84, HCFA was informed of 22 possible violations of the penalty provisions. Twenty of these, or 91 percent, involved Section 1882(d)(2), which prohibits a person from falsely representing an association with the Medicare program or any Federal agency for the purpose of selling or attempting to sell health insurance. Two cases involved an alleged violation of Section 1882(d)(3), which prohibits a person from knowingly selling duplicative health insurance to an individual entitled to Medicare, where such a policy will not pay duplicate benefits. Of the complaints received, 5 are being or have been investigated by specific State insurance departments, 15 were closed by HCFA due to lack of evidence, and 2 are being investigated by or have been investigated by the OIG.

Additionally, HCFA was able to close out 21 cases which were pending from prior fiscal years. Of these cases, 15 were closed by State insurance departments for lack of evidence, and 6 resulted in State administrative sanctions.

DIFFICULTIES IN PROSECUTION

Witness reliability has continued to be a problem in getting cases prosecuted under Section 1882. The elderly often become confused under questioning, and prosecutors are reluctant to charge agents under Federal law, since criminal penalties are called for. They feel that administrative penalties are more appropriate in many cases.

There is still interest at the State level in utilizing Federal penalties to prevent abuse and fraud in the sale and marketing of Medigap policies. Most States still do not have specific laws for violations involving Medicare supplemental health insurance. As indicated, however, getting these types of cases prosecuted under Federal law has proved difficult, and there have been no convictions to date under this law. At the present time it is felt that it is in the best interest of elderly citizens to continue the penalty provisions of Section 1882, to keep available the option of prosecution under Federal law.

* U.S. GOVERNMENT PRINTING OFFICE 1988; 208-375/80131

CMS LIBRARY
3 8095 00012350 1

U.S. Department of
Health and Human Services
Health Care Financing Administration
HCFA-02159
I.C.N.-000700